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DESIGN OF A MOCK CIRCULATION LOOP FOR THE VALIDATION OF AN ARTIFICIAL HEART

SAXION UNIVERSITY OF APPLIED SCIENCES, MECHATRONICS

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Summary

For this graduation project, research was conducted on the designing of a test platform for artificial hearts. This concept is part of the Holland Hybrid Heart consortium, which is working on developing an artificial heart for use in the human body. The research took place at the mechatronics and Robotics department, which is also involved in the consortium and responsible for the monitoring and sensoring of the hybrid heart. A problem statement was formulated to define the design assignment. The plan of approach outlines a 20-week schedule with different project phases and the research methodology that is used. The ultimate goal is to develop and create a test setup, which will serve as test platform for the research group to monitor and sensor the hybrid heart.

Heart decease lead to serious chronic health issues and van sometimes results in death. Although heart transplantation can address this problem, there is a chronic shortage of donor hearts, which is why mechanical solutions are being considered. Currently, many Ventricular Assist Devices are being developed to increase the life expectancy and improve the quality of life for patients with end-stage heart failure. Ventricular Assist Devices are a type of mechanical circulatory support device used when one side of the heart is not functioning properly.

Hydraulic circuits are designed to mimic the human circulatory system and are often referred to as mock circulation loops. To understand the components and functioning of the hydraulic circuit, research was first conducted on how the cardiovascular system works in the human body, as well as on precious studies related to mock circulation loops. Most of these loops are based on a circuit where a characteristic impedance is followed by a resistor and capacitor placed in parallel.

To translate this literature into the test setup's requirements, a set of requirements if first created to evaluate later concepts. Based on these requirements, a functional concept of a mock loop that mimics the human cardiovascular system is initially sketched. This design is further developed and eventually realised and tested. The hybrid heart can be connected to this mock circulation loop.

To operate the hybrid heart, a pneumatic circuit was developed. A custom data acquisition system that calculates and projects all test data in real time. With these components assembled, tests can be conducted on both the setup and hybrid heart. The performance of the hydraulic circuit and the drive unit was analysed under a wide range of conditions. The drive unit had a positive performance, achieving complete filling and emptying of the heart. The mock circulation loop also showed promising results in reaching pressures similar to those in the human body. However, after a failure in the hybrid heart, it became more challenging to test this performance.

Foreword

Before you is the thesis report titled “Test setup for an artificial heart.” This report details the development of a physical setup for testing and controlling an artificial heart. It was written to fulfil the graduation requirements of the Mechatronics course at Saxion University of Applied Sciences in Enschede. The research project began in February 2024 and was completed in August 2024. This report aims to serve as a valuable resource for researchers and designers interested in conducting tests or making modifications on the artificial heart or the test setup.

This assignment contains all three core aspects of Mechatronics learned throughout the course. Few assignments in Mechatronic education that focus on the medical field, making this project particularly unique and engaging. After this program, I plan to pursue a Master’s degree in Mechanical engineering, specifically in the track of Personalized Health Technologies. This made the assignment especially relevant and interesting to work on.

I would like to express my sincere gratitude to my supervisor, Maaike Hillerström, for her essential feedback and ideas during this process. The weekly update meetings were instrumental in guiding the project’s progress. I also extend my thanks to Matthijs van der Meulen, a researcher at Mechatronics and Robotics research group. He has assisted me technically and shared his ideas with me. Additionally, I am grateful to my supervisor at Saxion, Dick van der Meulen, for his advice on the report and what the requirements were from the study. Finally, I would like to thank all participants, experts and colleagues for their help during brainstorming sessions, webinars, prototype testing and monthly meetings with the entire consortium.

I hope you enjoy reading my graduation report.

Joris Blommestijn

Content

List with abstracts

Abstract	Word	Meaning
MCL	Mock Circulation Loop	The test-setup for an artificial heart.
CVS	Cardiovascular system	The blood circulatory system of the human body.
	In vitro	Research done in a laboratory dish or test tube.
	In vivo	Research done on a living organism.
CADs	Cardiac Assist Devices	Blood pumps that support the circulatory functions of severely ill cardiac patients
VADs	Ventricular Assist Devices	Is a device that helps pump blood from the lower chambers of the heart to the rest of the body.
SVR	System Vascular Resistance	Resistance against which the left ventricle must work to eject its stroke volume.
PVR	Pulmonary Vascular Resistance	Resistance against which the right ventricle must work to eject its stroke volume.
	Pulmonary circulation	The small circulation via the lungs to be re-saturated with blood.
	Systemic circulation	The big circulation that provides functional blood to all body tissue.
	Systolic	The blood pressure when the heart is contracting.
	Diastolic	The relaxed phase of the cardiac cycle when the chambers of the heart are refilling with blood.

1 INTRODUCTION

Heart failure (HF) is a major public health problem, with more than 23 million worldwide and the numbers continue to rise (Bui et al., 2011). The outcomes for people with HF are unacceptable and in advanced stages can be worse than many cancers. In addition to the risk of death, HF has a major long-term impact on a patient's health and well-being (Askoxylakis et al., 2010).

For patients with advanced HF, the future is currently very uncertain. Current treatment options include drug support requiring hospitalisation, implantation of a long-term mechanical circulatory support device (MCSD) or transplantation of a donor heart (HollandHybridHeart, 2022). Heart transplantation remains the preferred treatment for patients with advanced HF. However, this therapy is accessible only to a select group of patients. Only patients with a high survival rate can be placed on the waiting list. Moreover, the waiting list is still very long, with more than a thousand patients on the list in the EU by 2023 (Stewart, 2024).

The consortium of the Holland Hybrid Heart aims to develop an artificial heart, which completely replace a patient's heart in a procedure similar to a heart transplant, to provide a cure for heart failure patients. The consortium aims to improve the life expectancy and quality of life for advanced heart failure patients. To achieve the ambitious goal of providing a permanent solution, the consortium is simultaneously developing the key components of the hybrid heart. These include a soft robotic shell containing actuators and sensors, an inner lining engineered with tissue to ensure compatibility with blood-contacting surfaces, and a wireless energy transfer system (HybridHeart, 2020). Together, these components will form the total artificial heart that is soft, adaptable and wireless. By the end of this seven year project, the functionality and biocompatibility of the heart will be show in a proof-of-principle study in the sheep model, as shown in Figure 1. The project started a year ago and is now in phase one, focusing primarily on the development of the soft robotics.

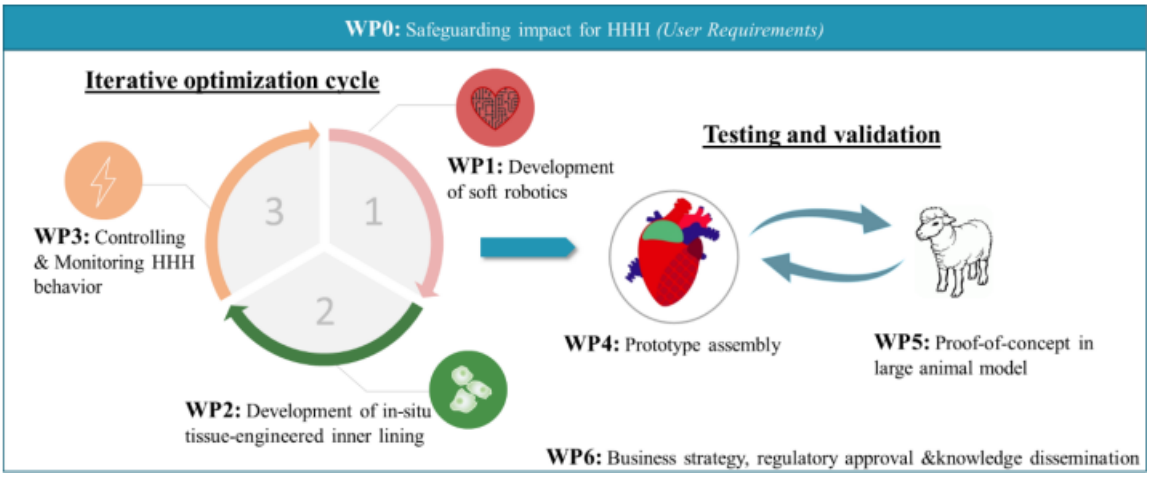


Figure 1: HHH development cycle (HollandHybridHeart, 2022)

Assignment

The aim of this project is to design an experimental setup, known as a Mock Circulation Loop, for the Holland Hybrid Heart project that will be housed at Saxion. This setup will serve as an instrument for performing various tests and analyses to evaluate the performance, reliability and safety of the artificial heart. The test setup needs to mimic the pressures of the human vascular system. It must be capable of connecting a (concept) model of the hybrid heart, as this will be crucial for adding sensors and conducting measurements directly on and within the heart itself as the project progresses. This connection would initially only be focused on one type of hybrid heart. Which heart this will be is determined later in the graduation project. The assignment also involves a design to actuate the hybrid heart. The Mock Circulation Loop in combination with the actuation, will give the basis to perform tests on the hybrid heart and adding sensors in the future. This test setup will support the SMART research group, which is responsible for work package 3 of the Holland Hybrid Heart project, focused on the monitoring and controlling of the heart. By having the Mock Loop on-site, the Mechatronic group can perform tests on the heart independently, without needing to rely on external research facilities. Additionally, the setup will be available to other research groups within Saxion that are also involved in the Holland Hybrid Heart project.

Plan of approach

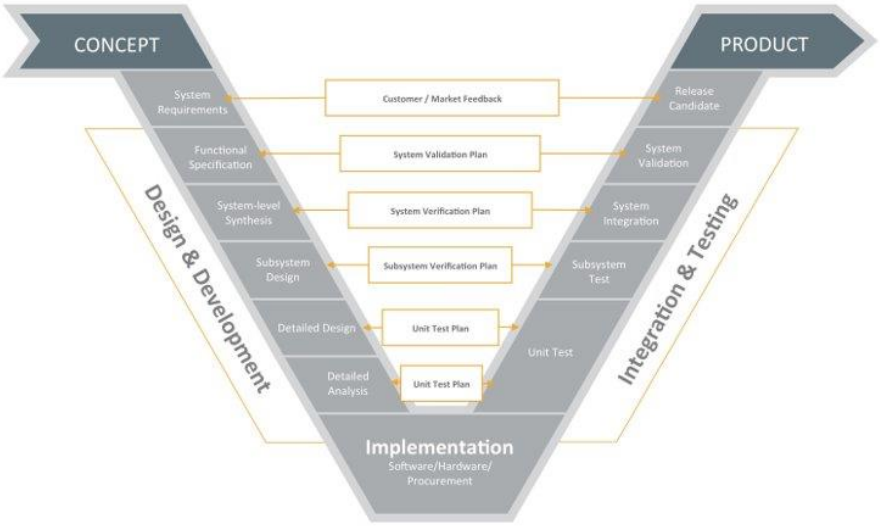


Figure 2: V-model (Jenkins, 2017)

In this project, the V-model is used as guideline. This model was chosen because of its structured approach, which ensured that each development phase, from requirements analysis to implementation and testing, was thoroughly validated and verified. Figure 2 provides an overview of these phases and their activities. The first phase is the research and analysis phase, which is essential for acquiring the necessary knowledge to compile the requirement document. By using the V-model, I was able to systematically translate the requirements into a detailed design, test each component and integrate it into a reliable and functional system. A technical design was then developed from the functional design. The components needed for this design are checked with the previously established requirements. Following this, the product development started. During which the technical documents created in the design phase were used to assemble the actual product. In this phase, most of the mistakes came to light and required a re-evaluation. These mistake were detected using unit tests. As last the final test to see if all the components work together. With this approach, mistakes were easily detected and solved. This improved the quality of the Mock Loop.

2 ANALYSIS

In this chapter, the realisation of the requirements and the most important requirements are briefly discussed. Before establishing these requirements, research was conducted to ensure a solid foundation for the design process. From the conclusion drawn from this research, requirements were identified that the test setup should meet. The requirements are a guideline and ensure that the final product does not deviate too much from the ultimate goal. Additionally, I took into account the pre-existing requirements set by the Holland Hybrid Heart project.

To further clarify and validate these requirements, I held regular meetings with my supervisor, researchers from the SMART Mechatronics research group and Maziar (Designer of LIMO Hybrid Heart), whose insights were crucial in shaping the final set of requirements. Discussions were also held with the research group of functions and textiles. These discussions primarily focused on what they would like to test on the setup and what test modules they already have in their department. However, they were unable to provide concrete requirements for the setup, as they had not yet determined the specific test they wanted to perform. Because of this, I chose to give some requirements a bigger margins and make the setup modular so that there is room for adjustments in the future.

These requirements are S.M.A.R.T defined, meaning that the requirements are concrete and clear, see Appendices. In addition to the requirements a test method is also specified. Prototypes can then be tested and where necessary improvement points are implemented.

2.1 REQUIREMENTS

An extensive set of requirements is defined to highlight the most important requirements for the test setup, Table 1. The whole system requirement document is in the appendix-2 system of requirements.

Number	Requirement	Description	Bron
FE0101	The mock circulation loop should allow for the integration of the artificial heart prototype, enabling realistic testing of its pumping.	The mock loop connection to the hybrid heart is initially designed for one hybrid heart concept.	Client
FE0103	The test setup must be capable of adjusting parameters such as cardiac output systemic vascular resistance, and blood viscosity to mimic the physiological conditions.	With the ability to adjust the parameters, different scenarios can be performed on the test setup.	Literature
TE0201	Left ventricle outflow pressure	90 – 120 mmHg	Requirements HHH
TE0202	Right ventricle outflow pressure	10-30 mmHg	Requirements HHH
TE0203	Left ventricle filling pressure	15 mmHg	Requirements HHH
TE0204	Right ventricle filling pressure	10 mmHg	Requirements HHH

FE0106	The test setup is capable of adjusting the pressure set on the heart.	By controlling the pressure to the heart, the heart pumping action and pressure will change	Client
TE0209	Heart rate	60 – 120 BPM	Literature
TE0210	Systole time at heart rate of 60 BPM	300 ms	Literature
TE0211	Diastole time at heart rate of 60 BPM	700 ms	Literature

Table 1: Extensive set of requirements

These requirements are important to ensure that the test setup accurately simulates the conditions of the human circulation system. By meeting these requirements, the test setup will be able to integrate the hybrid heart prototype and allow realistic testing of its pumping functions. The ability to adjust parameters is essential for replicating physiological conditions. Testing these requirements will show whether the test setup can serve as a basis for the tests the research group of mechatronics wants to do in the future.

2.2 Overview functional subsystem

The setup is divided into two subsystems. The hydraulic system for test and measurements (Mock Circulation Loop) that mimics the pressures of the human vascular system and the actuation of the heart. The Mock Loop is divided into two parts. A pulmonary part for the lung cycle and the systemic part for the body cycle. Both cycles contain a pre-load to fill the heart and a afterload, a pressure created by the vessels of the human body.

The actuation of the heart is also divided into two parts. A diastole part, that is responsible for the relaxing phase of the heart so the heart fills itself with blood. A systole part, that is responsible for the contracting of the heart so the blood is pumped through the Mock Loop. An overview of this subsystem is made into a block diagram in Figure 3.

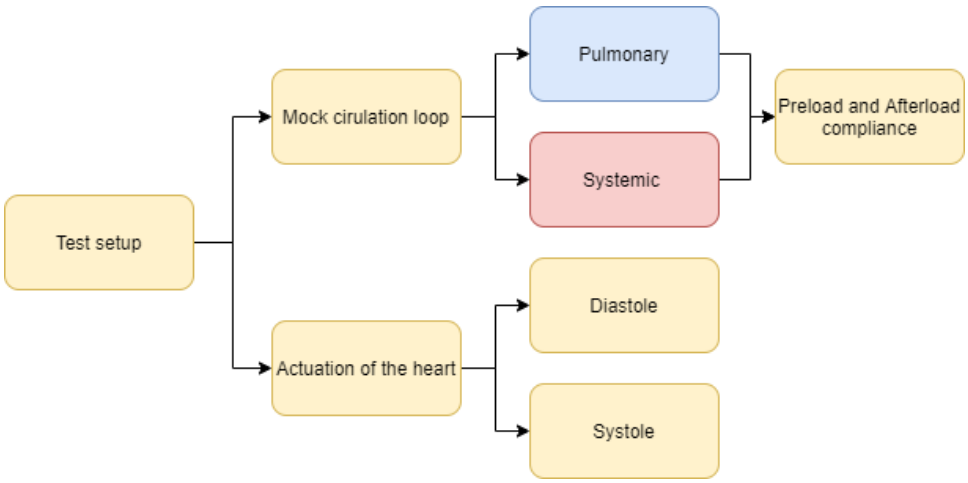


Figure 3: Blockdiagram subsystems

3 BACKGROUND AND LITERATURE REVIEW

To provide a clear understanding of what is required for the design of a mock circulation loop, research was done into the human circulation system and all of its components.

3.1 CARDIOVASCULAR SYSTEM

The cardiovascular system (CVS) consists of a heart, the network of vessels distributing blood to organs throughout the body and the vessels leading to the lungs where blood receives oxygen (Cappon et al., 2021). The oxygenated blood flows from the lungs into the left atrium and continues through the heart valve in the left ventricle. The heartbeat generates a wave of pressure and flow that travels through the aorta through a network of arteries. Here the oxygen inside the blood is transferred to muscles and organs. Blood then flows back to the heart, this cycle is called the systemic circulation. The blood now flows into the right atrium. The atrium fills the right ventricle with deoxygenated blood. The heart contracts and the blood is send to the lungs to oxygenate the blood again, this cycle is called the pulmonary circulation. From this point, the cycle of blood is through the body starts over to continually supply oxygenated blood to the whole body. The circulations are shown in Figure 4. Both the left and right ventricles face the task of overcoming systemic vascular resistance (SVR) and Pulmonary Vascular Resistance (PVR), respectively, to propel blood through the aorta and pulmonary to the arterial system (Gregory et al., 2010).

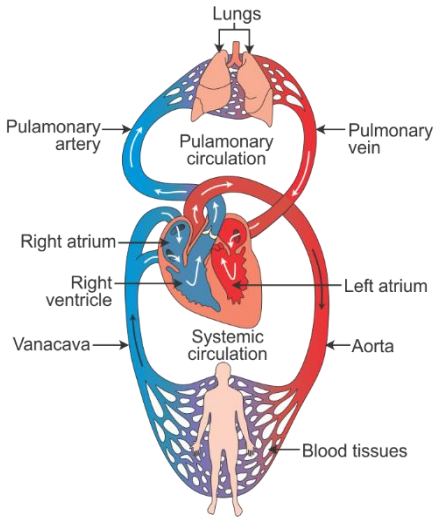


Figure 4: Cardiovascular system human body

3.2 CARDIAC CYCLE

The cardiac cycle, which is a series of events that take place from the start of one heartbeat to the beginning of the next, can be divided into five main phases:

1. **Atrial and ventricular diastole**: At the beginning of the cycle, ventricles are at their lowest volume and pressure. The chambers start to fill with blood, the valves between the atriums and ventricles are open, and the valves between the ventricles and arteries are closed.
2. **Atrial systole**: The atria contract, pushing blood into the ventricles. The ventricles then reach their maximum volume, known as end-diastolic volume. During the cardiac cycle.
3. **Isovolumetric contraction of the ventricles**: The ventricles begin to contract, but the pressure inside them is not yet high enough to open the valves at the arteries. The pressure

increases without any change in volume, and the valves at the atriums close as the atria enter diastole.

4. **Ventricular ejection**: The pressure inside the ventricles rises enough to open the valves at the arteries and blood is ejected into the major arteries. At the end of this phase, the ventricles reach their minimum volume, called end-systolic volume.
5. **Ventricular relaxation**: After the systolic phase, the ventricles start to relax, when the internal pressure drops below that of the aorta or pulmonary artery, the valves at the arteries close.

3.3 Compliance

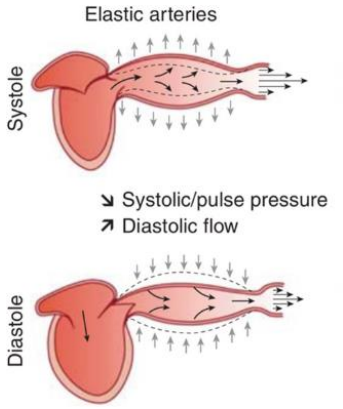


Figure 5: Compliance arteries

The afterload in the human body is created by elastic arteries. They are the closest to the heart and include the aorta, the pulmonary artery, and the right carotid artery. Their mechanical properties allow them to stretch during the systolic phase and yield during diastole through elastic recoil. During the systolic phase the pressure in the vessel increases, which stretches the vein as shown in Figure 5. This increases the volume of the vessel. In the diastole phase the extra volume inside the vessel gets pushed out. The contraction gives an afterload of the heartbeat. How much a vessel stretches depends on their compliance.

3.4 Mock Circulation Loops

To design and test biomedical devices, physical and computational models have become fundamental tools in the biomedical industry. The mock circulation loop (MCL) is one of these models. The MCL are an important *in vitro* platform for the designing and developing of Cardiac Assist Devices (CADs) and Ventricular Assist Devices (VADs). This has allowed the reduction of the amount of animal testing. In vitro studies do not require ethical approval and are much more cost-effective than animal studies (Bardi et al., 2023). That's why MCLs are used before *in vivo* studies. The main goal of the MCL is to mimic the operation and layout of the original cardiovascular system (CVS) as accurately as it can.

One of the first mock circulation loops (MCLs) was developed by Kolff in the 1950s (Kolff, 1959). This hydraulic system was capable of replicating both vascular branches and was designed to assess the performance of different total artificial heart (TAH) designs. Unlike the circuits that followed, Kolff did not use valves or tubes to replicate systemic resistance. Instead, he used water columns to generate pressure that opposed the movement of liquid throughout the circuit.

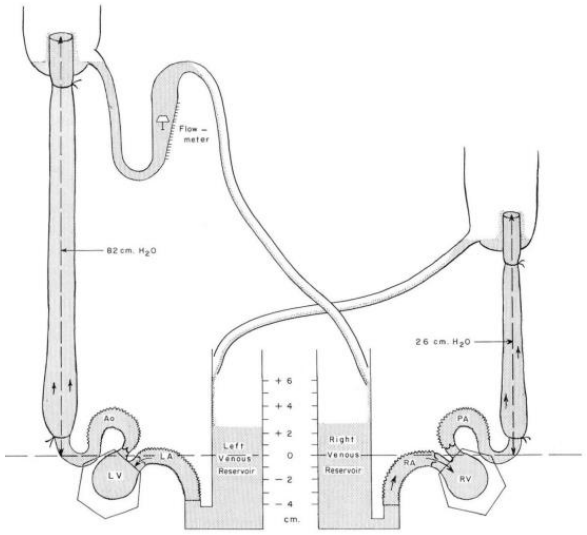


Figure 6: Kolff's MCL design (Kolff, 1959)

Later, Reul created a setup that could reproduce the physiology of systemic circulation without altering the natural shape of the heart and major arteries (Reul et al., 1974). They designed a polymeric biomorphic heart, as well as expanding and contracting aortas, using molds of human aortas. An external closed air chamber was used to achieve the desired compliance, while the ventricle was operated by a pressurized chamber.

During the 1960s, 1970s, and 1980s, new MCLs were developed for testing cardiac valves. Three different designs, all based on a three-element Windkessel model, were of particular interest. The first circuit used a Hoffmann clamp as the resistive element and an elastic polymeric tube for compliance (Bjork et al., 1962). The second and third designs both used a closed air chamber to create compliance. However, in one case, porous blocks were used to achieve resistance, while the other design used a piston to partially close a cylinder (Cornhill, 1977; Walker et al., 1980). All three setups used a pressurized chamber and a polymeric sac to mimic the pumping action of the heart.

Arabia identified two factors that had not been addressed in artificial heart testing, preserving the natural distribution of blood within various districts and the ability to vary the resistance and compliance of each district independently (Arabia & Akutsu, 1984). The first characteristic was achieved with attention to the volume of liquid in each element of the circuit. The compliant element was created with an air chamber equipped with an elastic membrane separating the air and liquid. A spring-mounted piston could be moved to adjust the compliance value. The resistive elements were created using long, straight, and stiff pipes, where the resistance could be altered by adjusting the length of the pipes.

A new method for creating physical cardiovascular models that has recently become popular is the use of hybrid mock circulatory loops (hMCLs). These systems combine both physical and mathematical models. It’s difficult to fully capture the complexity of the cardiovascular system in a physical model, and an accurate numerical model is needed for proper testing. By connecting a numerical environment, which is usually a computer simulation of the cardiovascular system, with a physical environment, which includes the device or component being tested, this problem can be solved.

The different methods from this research to create the compliance and resistance of the cardiovascular system, is used in the functional design of the Hydraulic system for test and measurement.

4 HYDRAULIC SYSTEM FOR TEST & MEASUREMENT

In this chapter, the requirements to design a Mock Circulation Loop and the theory how to meet these will be discussed. This theory will be put into functional and later in a technical design, eventually into the final setup.

4.1 REQUIREMENTS MCL

To evaluate the performance of the artificial heart, it must be connected to a Mock Loop to simulate the conditions of the human cardiovascular system. This setup allows for precise measurements and analysis of the heart's functionality under controlled conditions. The Mock Loop replicates the blood flow and pressure dynamics found in the human body, providing a realistic environment for testing. To achieve this, the Mock Loop must meet several critical requirements:

- Easy and accurate setting of compliance
- Continuous and wide range of achievable compliance
- Resistant to corrosion and degradation of blood mimicking fluids

4.2 FUNCTIONAL DESIGN MCL

In this chapter, different solutions to simulating the compliance of arteries and vascular resistance will be discussed. At the different solutions are compared to each other and checked with the requirements. At the end is an overview of the Mock Circulation Loop.

4.2.1 Compliant element

The compliant chambers are designed to mimic the dynamic fluctuations of blood pressure in the aorta. By flexibly expanding and contracting like blood vessels, they mimic the natural elasticity of the aorta. In essence, these chambers passively mimic the aorta's ability to stretch and retract in response to varying blood flow, mimicking the elastic behaviour of the aorta.

Closed air chamber

A closed air chamber is an air-tight reservoir that simulates arterial compliance by allowing the air inside to compress and expand in response to changes in fluid pressure. When fluid is pumped into the chamber, so the fluid pressure increased. The air within the chamber compresses, effectively absorbs the pressure increase. As the pressure decreases and the fluid flows out, the air inside the chamber expands back to its original volume. This process mimics the elasticity of arteries, where the change in air volume within the chamber represents how accommodate changes blood pressure(Reul et al., 1974).

Advantages:

- **Simple design:** The straightforward construction of the air-tight chamber makes it easy to build and integrate into a mock loop system, with fewer components reducing the likelihood of mechanical failure.
- **Adjustable compliance:** By changing the chambers air volume inside, it's possible to simulate different levels of arterial compliance.
- **Cost-effective:** The simple design also results into a cost effective solution.

Disadvantages:

- **Limited accuracy:** While this method can simulate basic compliance, it may not accurately capture the dynamic response of real arteries, varying in flow rates and pressures.
- **Lack of realistic behaviour:** The closed air chamber does not replicate the mechanical properties of arteries, such as the viscoelasticity and non-linear stiffness.

Closed air chamber with a spring

This method combines an closed air chamber with a spring to introduce mechanical resistance, which replicates more closely the elasticity and resistance of arteries. As fluid pressure increases, the spring compresses. This is adding resistance and allowing the chamber to expand in a controlled manner. When the pressure decreases, the spring decompresses. This is helping the chamber to return to its original shape. This setup simulates the elastic and resistive properties of arteries more accurately than a simple air chamber.(Arabia & Akutsu, 1984)

Advantages:

- **Realistic Compliance:** The addition of a spring allows the system to better mimic the natural elasticity and resistance of arteries, responding to pressure and flow rate changes in a manner that more closely resembles real arterial behaviour.
- **Enhanced Flexibility:** The spring's stiffness can be adjusted, providing fine-tuning of compliance characteristics to match specific physiological conditions more precisely.

Disadvantages:

- **Complexity:** The introduction of mechanical components like a spring increases the complexity of the design, making it more challenging to construct and integrate into the mock loop.
- **Higher Cost:** This system is typically more expensive to produce and maintain compared to a simple air-tight chamber due to the added components and the need for precise calibration.

Elastic Membrane

An elastic membrane consists of a stretchable material enclosed within a chamber. As fluid pressure changes, the membrane expands and contracts, much like a real artery. This method mimics the compliance of arteries by simulating the way they naturally expand under pressure and return to their original shape when the pressure is reduced (Walker et al., 1980).

Advantages**:**

- **Realistic Behaviour:** The elastic properties of the membrane closely approximate the natural elasticity of arteries, making this method a good representation of how real arteries behave under pressure.
- **Adjustable Compliance:** The material properties and the chamber design can be adjusted to simulate different levels of arterial compliance, allowing for customization based on specific experimental needs.

Disadvantages**:**

- **Durability:** Over time, the elastic materials used in the membrane can wear out or degrade. Especially with repeated use, which may affect the accuracy and longevity of the simulation.
- **Complex:** Installing and calibrating the membrane requires precision to ensure accurate simulation, making the setup more complex than a simple air chamber.

Variable Compliance Chamber with a Pneumatic System

A variable compliance chamber with a pneumatic system allows for dynamic adjustment of the chamber's volume and pressure. This system can simulate a wide range of arterial compliance behaviours by adjusting the air pressure within the chamber in real time. As the flow conditions change, the pneumatic system adapts the chamber's compliance. This is providing a highly versatile and responsive simulation of arterial behaviour(Petrou et al., 2019).

Advantages**:**

- **Dynamic Adjustment:** The pneumatic system allows for real-time changes to the chamber's compliance, making it possible to simulate various physiological conditions accurately.
- **Versatility:** By adjusting the air pressure, the system can replicate a wide range of compliance behaviours, making it suitable for a broad spectrum of experimental scenarios.

Disadvantages**:**

- **Complexity:** This method requires advanced control systems and sensors, which increases the complexity of the design and operation. It also demands more technical expertise to manage effectively.
- **Higher Cost:** Due to the advanced components and technology involved, this system is more expensive to produce and maintain compared to simpler methods.

Conclusion compliant element

The variable compliance chamber with a pneumatic system offers the highest level of flexibility and accuracy in simulating arterial compliance. It is more advanced and diverse than the other methods but it comes with more increased complexity and a numerical model is needed to work. This is not doable within 6 months. Both the membrane as the chamber with spring offers a more realistic simulation of arterial compliance. The membrane is not very durable and in complex in its installation, so the favour would go to the chamber with a spring.

The two options left are the closed air chamber with and without a spring. While a closed air chamber offers a basic and cost-effective method for simulating arterial compliance, an air-tight chamber with a spring provides a more accurate and dynamic simulation. However, this improved realism comes with increased complexity and cost. Because the setup will be mainly used to do monitoring and sensoring on and in the hybrid heart and not to improve it, the basic way to simulate the compliance is accepted. It is also the first version of the test-setup. to finish the setup in time and to watch the budget, is there chosen for the closed air chamber to simulate the compliance.

4.2.2 Resisting valve

To mimic the resistance in the cardiovascular system of the human body, an obstruction in the tube is needed. Although the tubes have a resistance of their own this is not enough to mimic the body's resistance. Also, the resistance in the body fluctuates quite a bit and is also different for each person (Timms et al., 2005). With this reason, it is convenient if the resistance of the setup can be easily adjusted. The following, are some options to create this resistance and the benefits per solution.

Porous blocks

One way to create resistance is with the use of porous blocks. This involves forcing the "blood" through the block. The narrowed passageways in the block create a pressure drop. To calculate the pressure drop, Darcy's equation is used (Brown, 2002):

$$Q = \frac{k * A}{\mu * L} * \Delta P$$

Where k $[m^2]$ is the permeability of the substance, A $[m^2]$ is the cross-sectional area, μ $[Pa * s]$ is the dynamic viscosity, Q $\left[\frac{m^3}{s}\right]$ is the volume flow, L $[m]$ is the length of the block, and ΔP $[Pa]$ is the pressure gradient.

The equation suggest that within porous elements, the relationship between pressure drop and flow is linear. However, In practical applications, the transitional area between the porous elements and the pipe introduces non-linear behaviour. Another major limitation to these components is the difficulty in creating a variable resistance. A way to still control the resistance is by putting a piston over the block. By compressing the porous block, the permeability is changing and thus controlling the resistance (Lacchè, 2017).

Solenoid valves

A solenoid valves is an electromechanical operated valve. The magnet inside the solenoid moves a piston up and down. This movement determines the dimension of closing of the orifice, which changes the flow resistance through the system. These valves are used often in MCLs, because they are quite cheap, easily accessible and their performance are detailed in their datasheet (Timms et al., 2005). A withdraw of this valve is that is in direct contact with the fluid in the system. This is restricting the types of liquids that can be used due to compatibility issues.

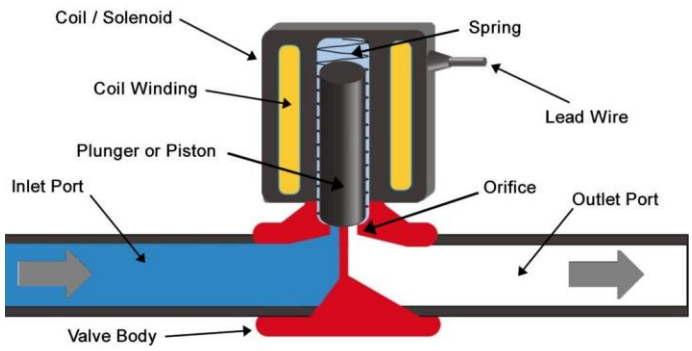


Figure 7: Solenoid valve (Putra, 2022)

Pinch valves

Pinch valves works by compressing the tube where the liquid is flowing through. By pinching the tube the orifice becomes smaller, so the flow resistance goes up. This is very similar to the solenoid valve, but in this case, the liquid never comes in contact with the valve, which allows blood to be used in the circuit. Just like the solenoid valves are these inexpensive, accessible and have a detailed performance. These valves show a quadratic drop in pressure with respect to variations in flow rate.

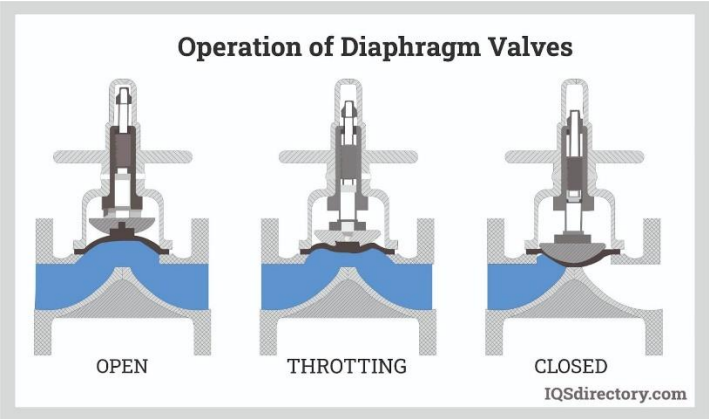


Figure 8: Pinch valve ("Leading Zero Static Valve Manufacturers,")

Hoffmann clamp

A Hoffmann clamp consists of a fixed plate and a movable plate, which can be adjusted by turning a screw mechanism. Acting as a manual pinch valve, a tube can be placed between the acting and the fixed plate. By turning the screw, the tube can be compressed, allowing the resistance to be adjusted. Although the Hoffmann clamps have been used in mock circulation loops before, their main drawback is that they exhibit a quadratic pressure drop in response to changes in flow rate.

4.2.3 Mock Circulation Loop overview

Put all the resistance and compliance components into a schematic sketch, it looks like Figure 9. This Mock Loop setup mimics the CVS of a human body. This setup is a double circulation loop. The *pulmonary* and *systemic* circulation. The Mock Loop is a platform for in vitro tests of and on the hybrid heart.

The setup functions in a way that allows the Hybrid Heart prototypes to pump “blood” into both circulations. From the right ventricle of the Hybrid Heart, the “blood” is pumped into the pulmonary circulation of the mock loop setup. To replicate the physiological pulmonary, an afterload (pulmonic blood pressure) is set and pulmonary resistance is set to balance the pressures between preload and afterload. After passing through the pulmonary resistance, the “blood” enters the preload chamber, which is set to a filling pressure that mimics the left atrium. The preload chamber pushes the water inside the left ventricle. The “blood” is then ejected by the left ventricle of the Hybrid Heart into the systemic circulation with an afterload set to the mean aortic blood pressure and a peripheral resistance corresponding to systemic resistance in the body. The “blood” subsequently returns to the right atrium, which fills the right ventricle.

To actuate the artificial heart, a pneumatic circuit is built in. This circuit is to control the actuation of the Hybrid Heart. Both the sensors of the Mock Loop and the sensors/valves of the pneumatic circuit are controlled via the control box. This reads out all the sensors in the setup and controls the heart. Here the heart rate and the pressure of the heart pumping can be set.

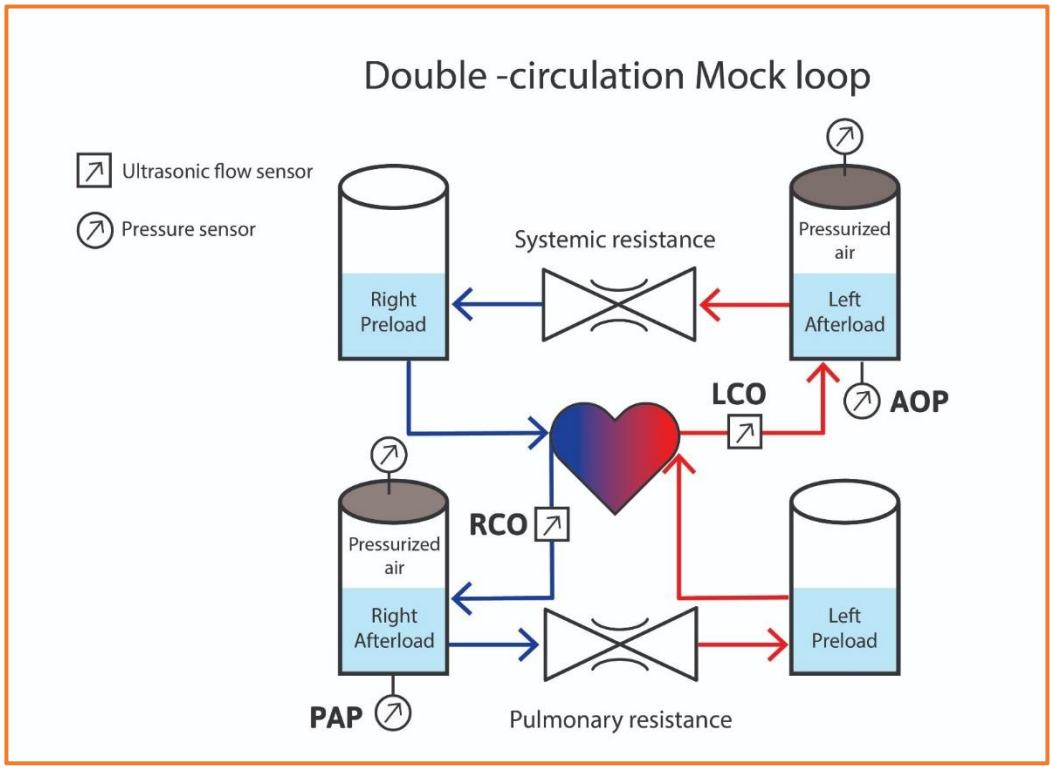


Figure 9: Schematic overview Mock Circulation Loop

4.3 TECHNICAL DESIGN MCL

In this chapter, the technical design of the Mock Loop is outlined. First, the hydraulic parts are being covered, particularly the ones that simulate the compliance. Calculations are performed on the dimension of the components and what parts they are made of. For a visualisation, the test setup is recreated in SolidWorks. After that, the necessary sensors for the setup are identified and how they are read out software-wise. Lastly, the mock loop is shown and the results of the tests on the mock loop.

Hydraulic components

Compliance chambers: The compliance chambers are present to passively mimic the rise and fall of the blood pressure in the aorta. This is representative of the ability of the blood vessel to expand and contract due to its own elasticity. The compliance is split into two parts, the systemic and pulmonary preload and afterload.

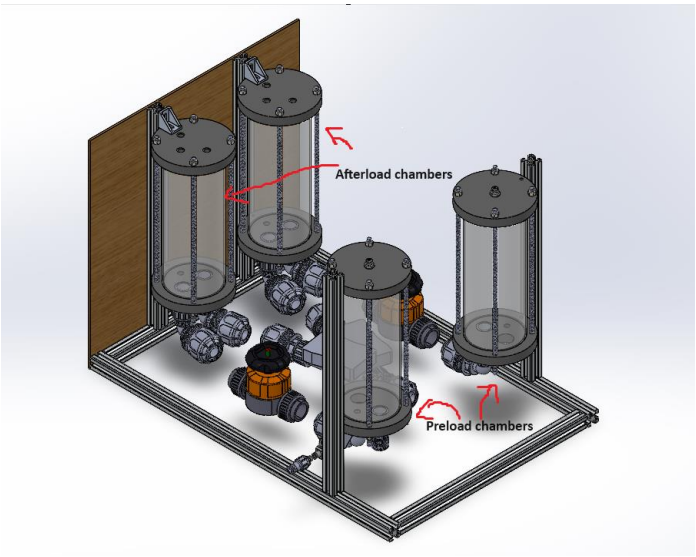


Figure 10: Preload and afterload chambers

Preload

To simulate the atriums of the human body free surface chambers are used. The atriums have a constant pressure on the hearts ventricles. In the relaxing phase of the heart, the pressure in the atriums is higher that the pressure inside the ventricles. When this happens the valves will be pushed open and the blood will flow into the heart chambers.

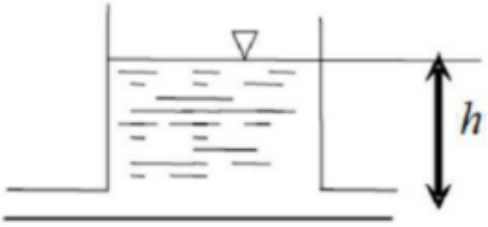


Figure 11: Free surface chamber (Rompani, 2021-2022)"

A free surface chamber is one of the simplest and most effective methods of achieving compliance and mimicking the atriums. The compliance value is derived by comparing the volume increase with

the corresponding pressure increase at the base of the chamber. This pressure can be calculated using the following equation:

$$p = \rho * g * h$$

Where $\rho \left[\frac{Kg}{m^3}\right]$ the density of the liquid, $g \left[\frac{m}{s^2}\right]$ gravitational acceleration and $h\ [m]$ the height of the level of the liquid.

In this case, the compliance (in ml/mmHg) is constant and depends on the geometry of the chamber:

$$C = \frac{dV}{dP} = \frac{Adh}{dh\rho g} = \frac{\pi D^2}{4\rho g} * \frac{10^6 ml}{m^3} * 132.84 \frac{Pa}{mmHg}$$

Where D is the diameter of the chamber (in m), ρ is the density of the liquid (in kg/m^3) and g is the gravitational acceleration (in m/s^2). s

The heart normally fills itself with the pressure inside the pulmonary and systemic atriums. These atriums are simulated with preload chambers. These are open air chambers made from acrylate. Their compliance is based on the geometry of the chamber and the amount of water inside the chambers. In terms of construction, the chambers have a diameter of 120mm and a height of 300mm.

To calculate the minimum height of the preload chambers the equations need to be rewritten. The minimum height of the chamber is calculated on requirement TE0203. This is done because this ventricle has the highest filling pressure. By calculating the height of the level of the liquid needed to create this pressure, we also have the minimum height of the chamber.

$$\rho = 15\ [mmHg] * 133.322 = 1999.83\ Pa$$

$$h = \frac{p}{\rho * g} = \frac{1999.83}{1000 * 9.81} = 0.2039\ [m] = \ 203.9\ [mm]$$

The inflow of the chambers is on the bottom and is done by regular pipe fittings. To secure watertightness, the chambers are sealed with an o-ring on the bottom and the top. The grooves in the bottom and lid of the chambers are done with the calculation program of Eriks (Eriks, 2024). The o-ring is set under pressure by four M8 threads tightened equally by a torque wrench. For the o-rings a round ring is chosen instead of a flat one. This is done because a flat o-ring needs a lot of pressure to be watertight. With this clamp setup, only low forces can be used to tighten the bolt. At the bottom of each preload chamber is equipped with a port for the filling and draining of the chambers.

Afterload

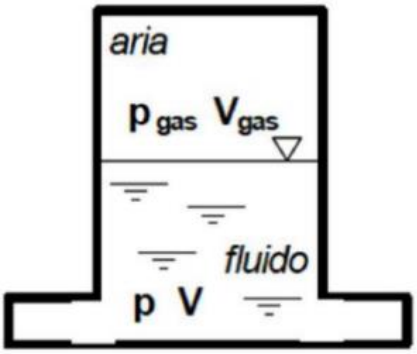


Figure 12: Closed air chamber (Rompani, 2021-2022)

Most arterial compliances are simulated by closed air chambers, as can be read in the literature review. Compliance, denoted as C and measured in ml/mmHg, is defined as the change in vessel blood volume (dV) relative to a given change in pressure (dP). The compliance equation is expressed as:

$$C = \frac{dV}{dP} = \frac{V_0 - V_1}{P_{0-P_1}}$$

The amount of air inside the chamber has a damping effect on the pulsing water pressure. The gas pressure inside the chamber is assumed to be consistent throughout its volume and matches the fluid pressure. The air volume within each compartment of the MCL was calculated under the assumption of adiabatic expansion and compression in the chamber. This is based on the belief that no heat exchange takes place between the compliance chamber and the environment during pumping cycles. In the case of adiabatic compression or expansion,

$$P_0 V_0^K = P_1 V_1^K$$

Where P and V are the absolute pressure and volume of the air inside the compliance chamber for the initial state (P_0, V_0) and after the systole or diastole (P_1, V_1) the adiabatic coefficient $K\ is \frac{7}{5}$ for air at 20°C (McGraw-Hill, 2002). Combining this with the compliance equation and assuming $P_1 = P_0 + dP$, compliance C can be expressed as:

$$C = \frac{dV}{dP} = \frac{V_0 \left[1 - \left[\frac{P_0}{P_{0+dP}}\right]^{\frac{1}{K}}\right]}{dP}$$

When determining the size of the chamber, the following two equations can be utilized. Once the chamber size is fixed, the formulas can be inverted to calculate the compliance.

$$V_0 = \frac{V_1 * P_1}{P_0}$$

$$V_1 = C * K * P_1$$

The primary chosen criteria for the compliant element are:

- Minimized component size
- Low costs
- Easy and precise compliance settings
- Continuous and wide range of achievable compliances

The afterload compliance is simulated with closed air chambers. The pressure inside the compliance chambers increases based on the flow rate generated by the Hybrid Heart. The compliance value is determined by the volume of air in the chamber. By filling the chambers with water and sealing them, the air inside the chamber can be adjusted to achieve the desired compliance values. The compliance allows the pressure inside the afterload to increase by a specific amount (eg 70mmHg to 120mmHg). If the compliance is not set correctly the pressure in the afterload might be higher or lower than the required amount even if the stroke volume is in the physiological range.

The air chamber was obtained by sealing the acrylate tube with two PVC 20mm thick plates. The chamber has a total of 3390 ml. Just like the preload, the afterload chambers are sealed with the same O-ring principle. The dimensions and the height of the chambers is also the same. This is done to lower the costs of the materials needed and also making the fabrication simpler. Just like the preload chambers the afterload chambers have the inflow at the bottom with the same regular pipe fittings.

On top of the chambers, a pneumatic port is placed with a valve. The state of this valve decides if the chamber is closed or open to air. This is useful for the filling and draining of the chambers. This pneumatic system can also be used to modify the initial volume and pressure of the air within the chamber. This can simply be done by connecting a high-pressure line or a vacuum line. To ensure that the pressure in the chamber gets too high and prevent the chamber from exploding, a pressure relief valve is placed at the top. To set the pressure relief valve, an analogue pressure gauge is placed on the lid of the chamber to measure the air pressure inside.

Once the initial pressure is measured and the initial air volume is calculated, equation:

$$V_1 = C * K * P_1$$

can be used to estimate the compliance the chamber will produce during the operation. Adding air to the chamber increases the initial volume and compliance. While removing air using the vacuum line decreases them. Adding more volume can further improve the compliance.

Resistor

This resistance is created by a diaphragm pinch valve. The resistor offers an obstruction in the flow of 'blood'. It is used to set the pressure difference between the afterload chamber and the preload chamber it is connected to. By increasing or decreasing the resistance the compliance in the afterload chamber changes. By turning the resistor to the wanted pressure difference, the same compliance is achieved.

Figure 13: Diaphragm pinch valve (Georg Fischer PVC-U 10bar Diaphragm Valve, 161514515)

There is chosen for this resistor because it has no direct contact with the liquid inside the test module. This means that blood can be used. Another advantage is that it is simple in control. This with the reason that everybody that wants to use the setup, knows how to operate it. It has highly precise resistance settings. Each turn the resistor moves so little that it is possible to accurately set the resistance. The Hoffmann clamp has the same advantages as the pinch valve and is also cheaper, but there is a concern that it is not accurate enough. Last feature why this type is chosen is it easy connection. It uses standard connections for pipes. This makes the assembly of the Mock Loop less complicated.

Sensors

Pressure sensors

Two pressure sensors are placed at the bottom of the afterload chambers. These sensors measure the pressure changes inside the afterload (aortic and pulmonary pressure). The 3500R0001G01B000 electronic pressure sensors were used. Which are rate at 7 V to 30 V and can measure pressures from 0 to 1 bar (750 mmHg), this is enough for the requirements TE0201 and TE0202. There is chosen for this sensor, because it is water resistant and has an accuracy of 0.25%.

Figure 14: Pressure sensor (RS)

Pin	Colour	Description
1	Black	Analog output (pressure)
2	Brown	Power supply +7-30 V
3	No connect	Analog output (temperature)
4	Blue	GND

Table 2: Input configuration

Flow sensors

To obtain the flow rate measurements, two JUMO ultrasonic analogue flow sensors are used to measure the output flow of the heart to measure the cardiac output. This flow sensor uses transit-time ultrasound technology to accurately (2% of reading) measure the flow rate without direct contact with the fluid. This is important because the flow inside the tubes needs to be laminar. The flow rate reading is based on the calculation of the difference between the transit time of ultrasound pulses propagating with and against the flow of liquid.

The sensor measures the flow in conductive and non-conductive fluids. The ultrasonic technology makes the meter wear- and maintenance free. The sensors is also metal-free and has a plastic tube, this makes the sensor corrosion free.

Figure 17: Ultrasonic flow sensor (JUMO)

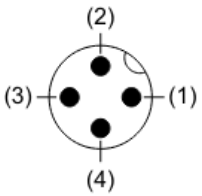


Figure 16: Connection diagram

Pin	Colour	Connection
1	Brown	Voltage supply (DC 24 V)
2	White	Analog output
3	Blue	GND
4	Black	Digital output

Figure 15: Port configuration

The flow sensor has an output of 4 to 20 mA. The NI DAQ reads the sensors in a voltage range from +/-10V. using a resistor a voltage output can be created. Ideally, we want to have a voltage from 0 - 10V, this because than we would have the most bits available so the data will be more accurate. Multiplying 0.004 A with 500 Ω we get an output 2V. Multiplying 0.020 A with 500 Ω we get an output of 10V. This is the most optimal range for the flow sensor to work in.

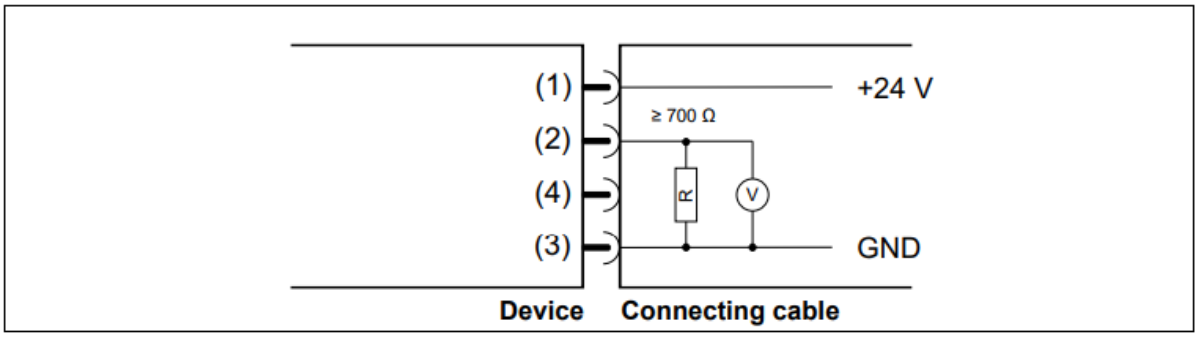


Figure 18: Connection circuit resistance flow sensor

Electronic circuit

To control and operate all the different valves and sensors in de mock loop an electronic circuit is built. To process and read all this data a NI DAQ 6001 is used. This is a data acquisition device that is USB-powered. It has 8 analogue input ports for monitoring the different sensors. Two analogue outputs provide control to the electronic pressure regulator and 13 digital output pins for controlling the solenoid valves of the system.

The power output of the NI DAQ is not enough to power all the sensors and actuators of the system. Therefore are they connected to the SLR-150-24. This is an AC to DC converter with a 24V DC output. All the electronic devices in the mock loop operate on 24V.

No.	Product	Purpose	Amount	Required voltage	Maximum power(each)	Available power	Power supply
1	VPPE-3-1-1/8-2-010-E1	Pressure Regulator	1	24V	4,2W	156W	LRS-150-24
2	MHE2-M1H-3/2O-QS-4-K	Pneumatic 3/2 solenoid valve	2	24V	2,88W		
3	3100r0010g01b000rs	Pressure sensor	2	8-30V	1W		
4	406050/000-0025-121-32-58-1	Liquid flow sensor	2	18-30V	10W		
5	NI DAQ 8451	I/O device	1	5V			Laptop

Table 3: Power supply requirements

The electrical circuit shown in Figure 19 connects all the sensors and actuators for the mock loop and heart actuation. This setup enables precise control and monitoring of the system's components. All the sensors are directly connected to the NI DAQ. The ground and supply voltage are connected to a distribution blocks, the ground and power line of the sensors are connected to these blocks. That way all sensors use the same ground. The electrical components are placed inside the control box. This is a splash watertight plastic box to prevent shortages or damage in the circuit.

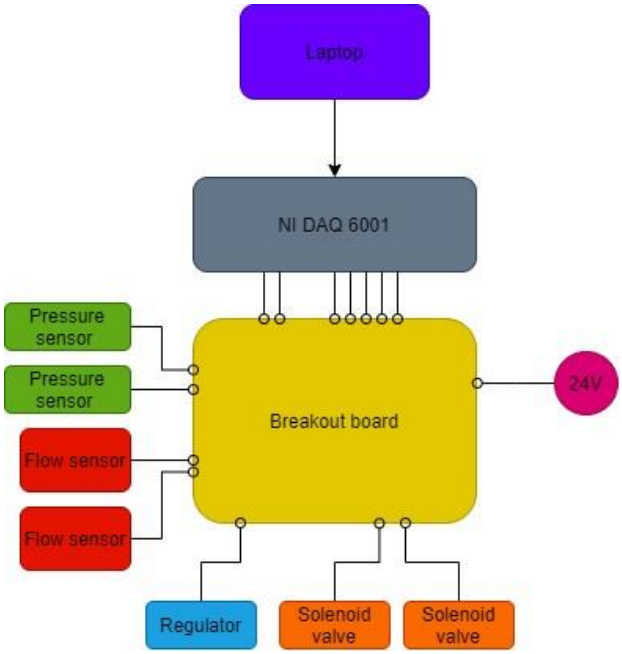


Figure 19: Schematic of electrical system

Software Sensors

The reading of the sensors in the Mock Loop takes place all within the same while loop. Inside the loop, the function ´DAQmx read´ reads the data from all the sensors. This data needs to be sorted, so an index array is used. Once sorted, the signals can be converted into useful data using the configuration formulas (LabVIEW software). This data is sent to an XY-graph for real-time visualization, with the elapsed time projected on the x-axis.

After each data point, the program waits a few milliseconds depending on the value of the variable ´seconds per data point´. Then, a new cycle of the while loop begins. When the stop conditions are met, the program asks if the user wants to save the data. If confirmed, the data is stored in a text file with headers at the top.

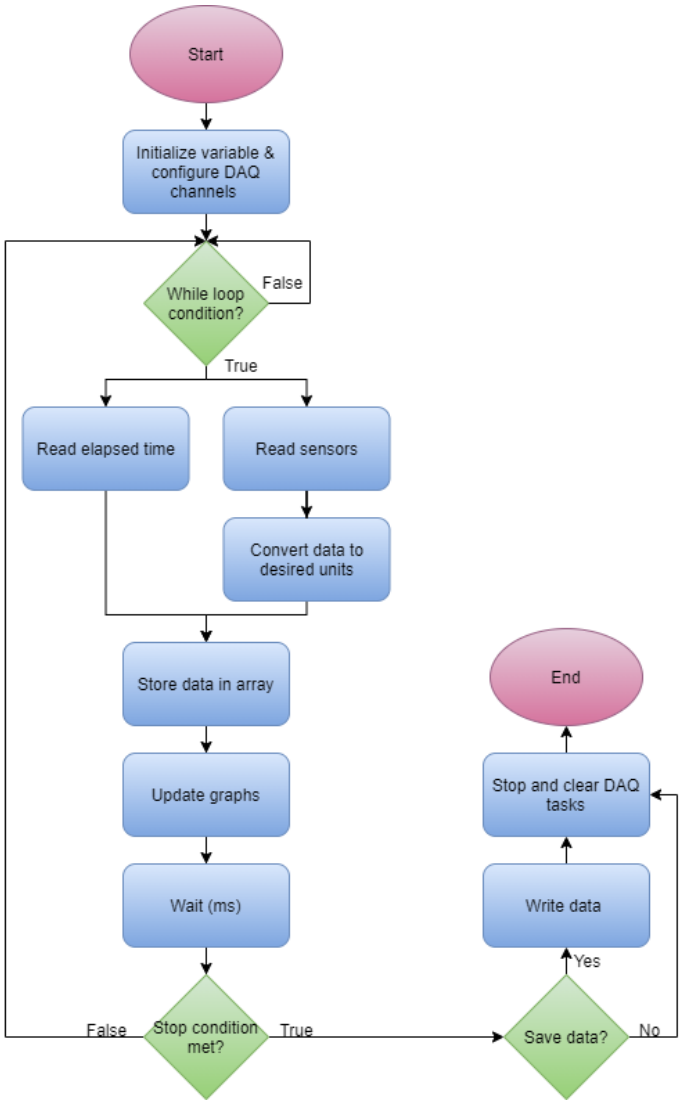


Figure 20: Flowchart LabVIEW code sensors

4.4 REALISATION + TESTS & EVALUATION

In the realisation phase of the project, the focus changed from functional design and technical design to implementation and testing of the system. In this phase, components are ordered, manufactured and assembled. During this process, each component was tested to ensure it met the specified requirements. This section presents the results of the realisation phase.

Figure 21: Preload chamber

Figure 22: Control box

4.4.1 Watertightness test

The purpose of this test is to verify that the mock circulation loop meets the water-tightness requirement (FE0401). Ensuring that the system is water-tight is crucial to prevent leaks, maintain pressure and ensure the overall integrity of the setup.

Method watertightness test

To test for water-tightness, the following procedure was followed:

1. *Preparation:* The circulation loop was assembled according to the standard setup instructions.
2. *Filling:* The system was filled with water, ensuring all air pockets ware removed.
3. *Pressurisation:* The loop was pressurized to the maximum operating pressure using a hybrid heart.
4. *Observation:* The entire system was inspected for leaks over a period of 24 hours.

Results watertightness test

The water-tightness test yielded the following observations:

- Leakage by the connection of the hybrid heart.
- Leakage by the connector from the preload chamber
- Leakage by the connector to the flow sensor.

Conclusion watertightness test

The mock circulation loop was mainly leaking by the connection points of the hybrid heart and the nearby connectors. The issue was caused by the connectors on the heart having a lower diameter that the external diameter of the tubes. This problem was resolved by wrapping electrical tape around the tube until it nearly matched the diameter of the hearts connectors. Additionally, using metal zip ties instead of plastic ones provided enough clamping force to ensure a watertight connection.

The connectors from both the preload chamber and the flow sensor were also leaking. This is due to the tube not being fully clamped into the connectors. With these adjustments the setup was not leaking anymore, requirement FE0401 is a pass.

An Interesting observation was the presence of an air bubble inside the tube that supplies the heart with “blood”. To prevent this, the inflow tube was placed lower than the outflow tube to make it easy to remove the air pockets. Despite this adjustment, the air pocket did not go away even with the system running. This issue will need to be addressed in future iterations.

4.4.2 Evaluation hydraulic system for test & measurement

The calculations of the compliance elements show that the pressures of the human body can be simulated in a chamber of 120mm diameter and with a height of 300mm. With these dimensions, there is still room to increase or decrease the compliance. The water test is used to assess the reliability of the test setup. With passing the test and following the requirements of Safety & regulatory and Environmental, the setup can be considered reliable and safe.

To verify that every sensor and component works as is should a subtest is performed. By these subtest both the sensor and a part of the software was tested. This was done by connecting the pressure sensor to air pressure and reading specific values, and by running water through the flow sensors. This demonstrates that the sensors and software are functioning correctly before being implemented in the setup.

5 ACTUATION OF THE HEART

In this chapter, the design of how the heart is actuated is discussed. The actuation is created using pneumatics. This is done because all the concept hearts that the Holland Hybrid Heart has produced make use of pneumatics. The heart used to verify the test setup with the requirements is the LIMO heart designed by M. Arfaee. This heart consist out of air pockets who are integrated to the sides of the ventricle. The pockets expand when air is blown into these pockets, this makes the inside of the ventricle smaller. This way the 'blood' gets pushed out. To fill the heart with blood the pockets needs to inflate, this creates a sucking effect. This effect together with the pressure delivered from the atrium will fill the heart with 'blood' again. The heart has two pneumatic connectors on both side of the ventricle.

Figure 23: LIMO hybrid heart

5.1 REQUIREMENTS ACTUATION

To know the performance of the Holland Hybrid Heart, the heart must first be hooked up to the Mock Loop so that measurements can be made on the heart. Now the problem is that the heart cannot "beat" yet. To make it work properly, a drive circuit is needed. The HH Heart, like other artificial hearts, is driven with pressurized air. The pneumatic network is used to actively control and monitor the drive side of the hybrid heart. We control the drive pressure and the duration of each "beat". The pneumatic circuit consists of the following requirements:

- Limited cost
- Fast switching between diastolic and systolic pressures
- Commercially available components
- High working pressure ranges
- Variable working speed
- Variable ratio of systolic and diastolic duration

The unit consists of a pneumatic circuit managed by an electronic system with an interface for adjusting test parameters.

5.2 FUNCTIONAL DESIGN ACTUATION

The pneumatic circuit consists of two branches. One provides positive pressure to the Hybrid Heart, referred to as the *systolic* line, and the other provides negative pressure for the *diastolic* movement of the heart. The circuit is connected on one end to the Septum of the hybrid heart, while the other end is connected to a high-pressure system through the use of pneumatic tubes.

Starting with the connection to the high pressure source, the first component in the circuit is an electronic pressure regulator. This regulator, which operates within a range of 0 to 2 bar, controls the pressure supplied to the hybrid heart. It was chosen for its high flow rate and accuracy, which are essential for conducting accurate test on the hybrid heart.

The next element is a pneumatic tank, which acts as a buffer tank to fill up the septum of the heart. The tank secures that the pressure in the system is stabilized by absorbing pressure fluctuations and maintaining a consistent output pressure. Is also acts as an energy reservoir, storing compressed air that can be used to meet sudden demands in air consumption without causing a significant drop in system pressure. At the systole phase the hybrid heart suddenly demands a significant amount of air volume to fill the septum. The next components are three-way solenoid valves, which are used to control the actuation of the hybrid heart. It allows for the switching between the positive pressure (systolic line) and negative pressure (diastolic line), this gives control over the inflation and deflation cycles necessary for simulation heartbeats.

The diastolic line is connected to a vacuum generator for quickly removing the air from the septum's inside. The component utilizes the Venturi effect to generate negative pressure from positive pressures present at the inlet. Between the septum and the vacuum generator a manual pressure regulator is placed to regulate the diastolic pressure. By default, the septum is connected to the vacuum generator through the solenoid valves to prevent the heart's actuator from exploding in case of an emergency.

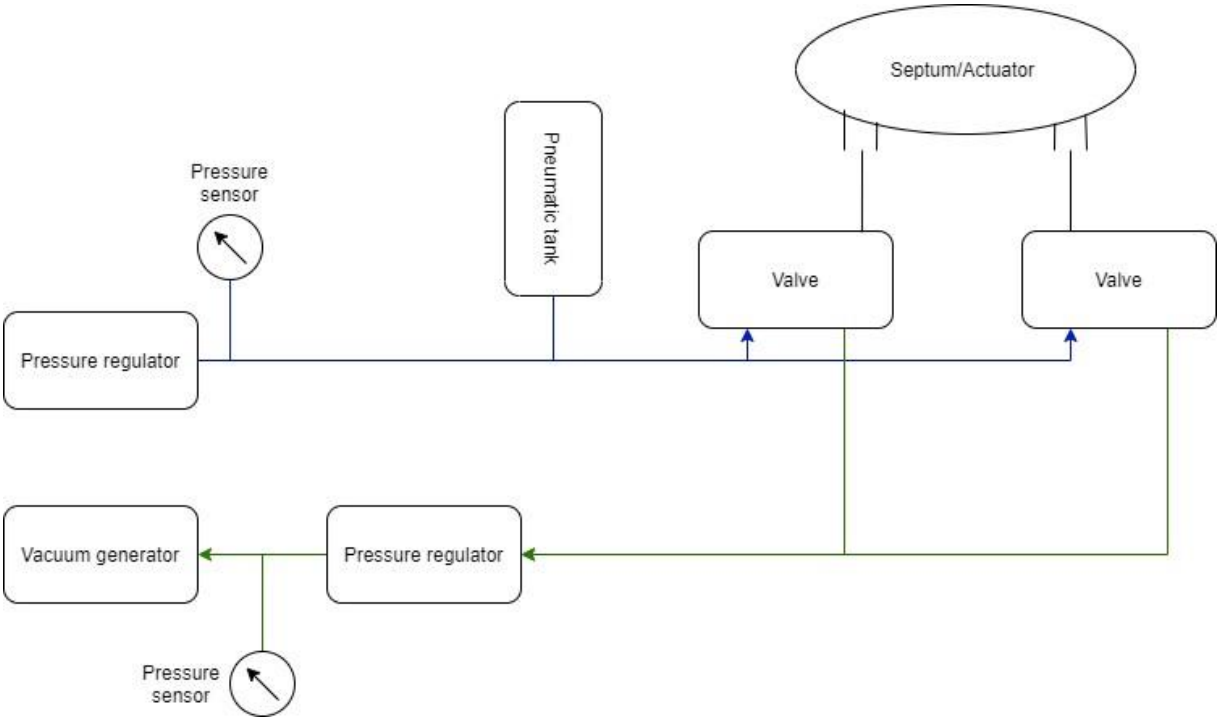


Figure 24: Schematic overview of pneumatic circuit

5.3 TECHNICAL DESIGN ACTUATION

Pressure regulator

In the pneumatic circuit, different types of pressure regulators are employed to accurately control the pressure across various sections of the system. Each type is designed to handle specific pressure ranges and provide precise control for different applications.

- Manual pressure regulator: 0.3 to 7 Bar pressure regulator from Festo (S4-LR-1/4-D6-AS) to control the pressure to the vacuum generator.

- Electronic pressure regulator: 0 to 2 Bar electronic pressure regulator from Festo (VPPE-3-1-1/8-2-010-E1) to control the pressure to the hybrid heart.

Figure 26: Festo electronic pressure regulator (FESTO)

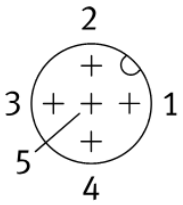


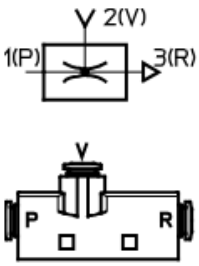
Figure 25: Connection diagram ((FESTO))

Pin No.	Colour	Assignment
1	Brown	+24 V DC
2	White	Analogue input
3	Blue	GND
4	Black	Analogue input '+' setpoint value (0-10 V)
5	Grey	Analogue output (0-10 V)

Table 4: Port configuration

Vacuum generator

The vacuum generator from Festo (VN-14-L-T4-PQ2-VQ3-RO2) rapidly evacuates air from the heart's actuator chamber, creating the necessary vacuum condition. This is critical in simulating the heat's diastolic phase, where the septum needs to contract quickly to mimic the natural heart movements. The generator utilizes the Venturi effect with a driving pressure up to 8 bar that generates a suction rate of 90L/min.



Port	Description
1	Input port up to 8 Bar
2	Vacuum port
3	Exhaust port

Table 5: Port connections

Figure 27: Festo vacuum generator ((FESTO))

3/2 solenoid valve

Solenoid valves from Festo (MHE2-M1H-3/2O-QS-4-K) are key components that switch between high-pressure and vacuum line. During the systolic phase, they direct high-pressure air into the septum, causing it to contract and mimic the heat's pumping action. During diastole, they switch to the vacuum line, allowing the actuator to relax and expand, simulating the hearts filling with blood. This precise switching creates a realistic heartbeat. This was chosen for its fast switching rate.

Figure 29: Festo 3/2 solenoid valve (FESTO)

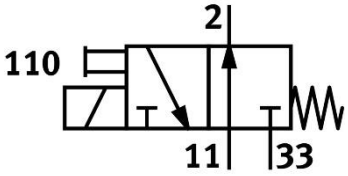


Figure 28: Circuit symbol (FESTO)

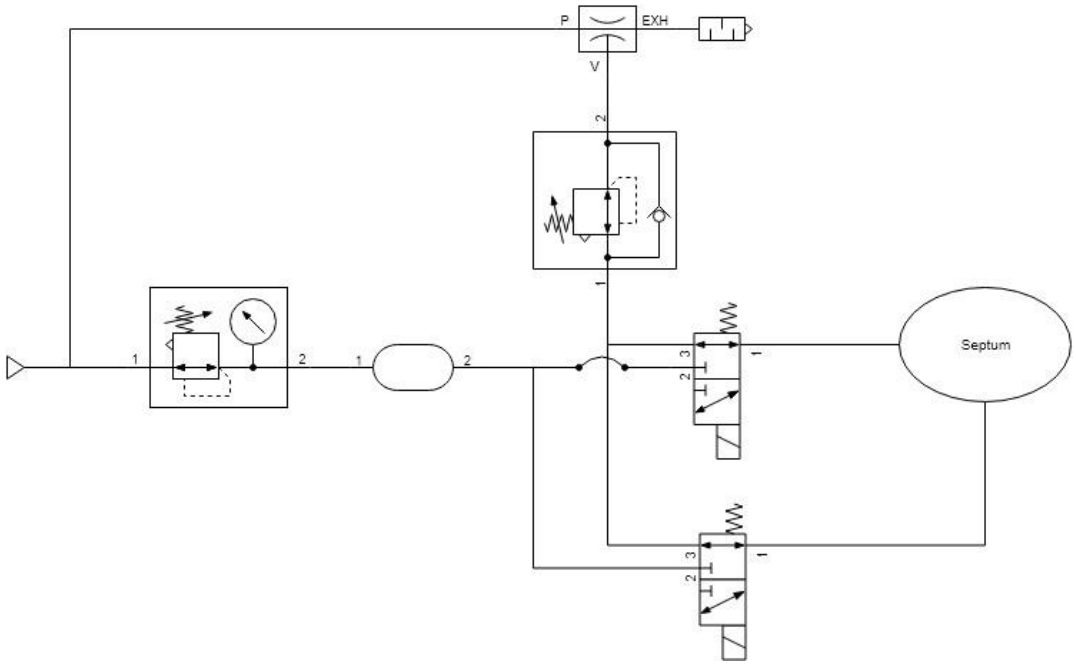


Figure 30: Pneumatic circuit to control the hybrid heart

High switching power circuit solenoid vales

The solenoid valves that mimics the diastole and systole of the heart need a significant amount of current to operate. The NI DAQ 6001 only has a small current output of 4mA per pin. The Solenoid valves use 24V and run on 2.88W, so it need 120mA to be turned on and off. These are controlled through the digital ports of the DAQ board by a high-power switching circuit using MOSFETs Figure 31(IRF breakout module). The MOSFET takes the small control signal from the microcontroller and switches a larger current to operate the solenoid valve. It isolates the microcontroller from the high current needed by the solenoid valve, protecting it from damage. Without the MOSFET, the circuit is likely to be unreadable and potentially damage the components. Using a MOSFET allows safe, efficient control of high-current devices like pneumatic solenoid valves by the low-current NI DAQ board.

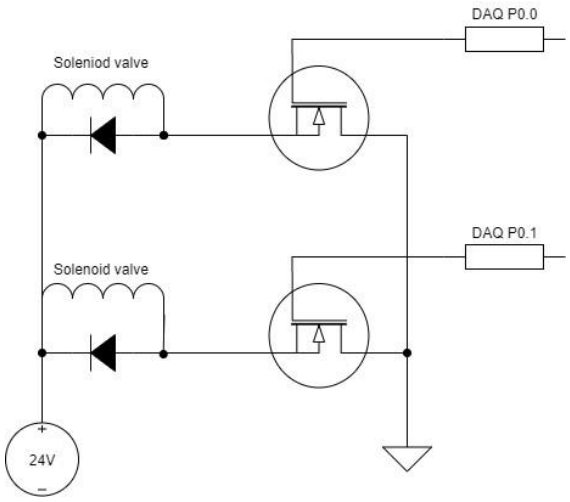


Figure 31: High voltage switching circuit

Gate (G): connected to the microcontroller. When the microcontroller sends a voltage to the gate, it turns the MOSFET on. Drain (D): connected to one terminal of the solenoid valve. Source (S): connected to the ground.

The I/O device sends a voltage to the MOSFET's gate. This voltage turns the MOSFET on, allowing current to flow from the drain to the source. The current flows through the solenoid valve, activating it and allowing the air to pass through. When the microcontroller stops sending voltage to the gate, the MOSFET turns off, stopping the current flow and deactivating the solenoid valve.

Flyback diode

Solenoid valves store electric energy in their magnetic field when currents flow through them. When the current is suddenly switched off, when the MOSFET turns off, the energy stored in the inductor can cause a high-voltage spike (inductive kickback) in the opposite direction. This high-voltage spike can exceed the voltage rating of the MOSFET, potentially damaging it or other components in the circuit. The flyback diode (1N4001GP-E3/73) provides a safe path for the current generated by the collapsing magnetic field, preventing the high-voltage spike. When the MOSFET turns off, the inductive kickback voltage conducts the diode forwards. Allowing the current to recirculate through the solenoid and the diode, and so discharging the energy safely.

Software solenoid valves

To create the ‘heartbeat’, the valves switch between blowing pressurized air into the septum and sucking it out with a vacuum. This is achieved by switching the state of the solenoid valve. Before entering the while loop, the user first has to put in the DAQ channels and initialize the variables.

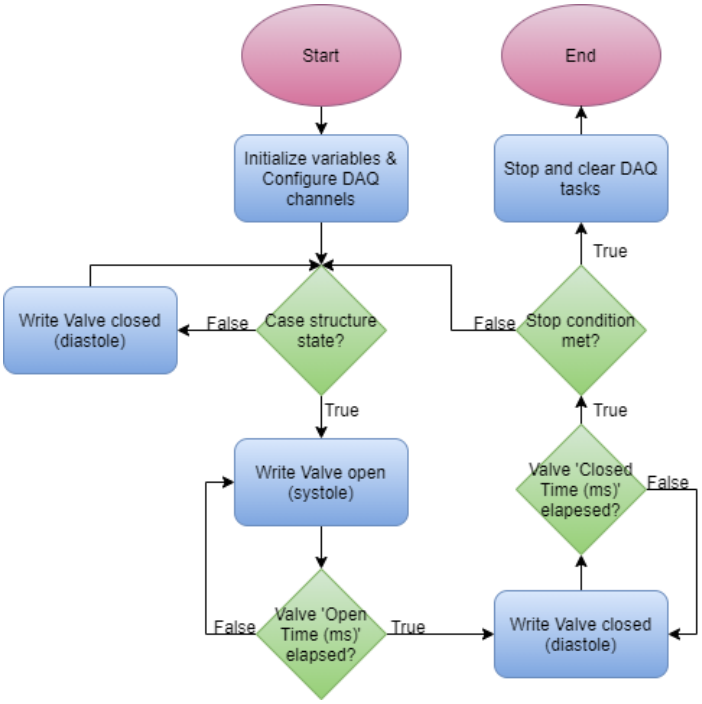


Figure 32: Flowchart LabVIEW code Solenoid valves

The actuation of the solenoid valves is in a separate while loop than the sensors, to prevent a drop in frames of the graph. Inside the while loop, the program checks if the case structure is true. Meaning that the start/stop button for the solenoid valves is pressed. When true, the program enters the first flat sequence structure. Here the program writes a true signal to the NI DAQ. Since the solenoid valve is ‘normally closed’, this signal opens the valve, allowing the pressurized air to pass through. The valve remains open for the duration specified in the ‘Open time (ms)’ variable.

After the ‘Open time (ms)’ elapses, the program proceeds to the second flat sequence structure. Here, it writes a false signal to the NI DAQ, causing the solenoid valve to switch to the vacuum line. The valve stays in this position for the duration specified in the ‘Closed time (ms)’ variable.

Then the program returns to checking the state of the case structure. If the start/stop button is not pressed, the case structure is false. This will write a false to the NI DAQ until the button is pressed. If the button is pressed mid-sequence, the program will complete that current sequence before stopping the solenoid valves. This is because the program only checks the case structure’s state at the beginning of each while loop iteration. The program stops immediately if an error occurs or the STOP button is pressed. The valve switches to the vacuum line to prevent damage to the hybrid heart.

Software pressure regulator

In the same while loop as the sensors is the writing and reading of the electronic pressure regulator. An analogue output line to set the right pressure for the hybrid heart and an analogue input line to read the pressure. The user first has to put in the DAQ channels and initialize the variables.

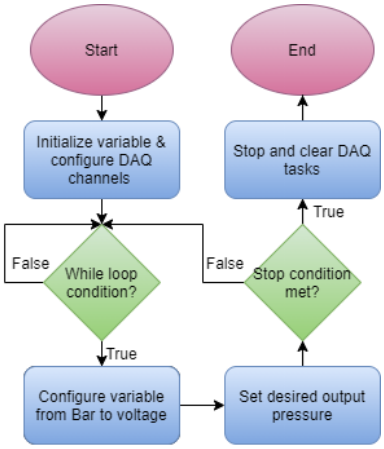


Figure 33: Flowchart labVIEW code pressure regulator

The analogue output line is a straightforward process that writes the output pressure to the pressure regulator. First, it converts the input variable from Bar to a voltage using the configuration formula of the pressure regulator. Then, it checks if the while loop state is still true, which is remains unless there is an error or the STOP button is pressed.

5.4 Realisation + tests & evaluation

In the realisation phase the technical design is turned into a finished product. This involved ordering all the components and then assembling them. During assembly, each component is tested individually to make sure everything functions correctly. This sections presents the results from the realisation phase.

Figure 34: Pneumatic system

5.4.1 Heart actuation test

The goal of this test is to check if the pneumatic system can consistently reach a range of heart rates from 60 BPM to 120 BPM (FE0106, TE0209). It also ensures that the diastole and systole durations are adjusted correctly as the BPM changes (TE0210, TE2011). This is important for simulating different heart conditions accurately.

Method

To test the heart actuation, the following steps were taken:

1. *Initial ballon test*: Before connecting the heart to the mock circulation loop, we first tested the system using a balloon. This step was done to make sure that the pressures would not be too high and potentially damage the heart mechanism.
2. *Setup*: After confirming that the pressures were safe with the balloon test, the heart actuation system was connected to the mock circulation loop. The mock loop was empty to test the beats per minute without any pressure inside the heart.
3. *Configuration*: the heart controller was set to achieve the following BPM targets: 60 BPM, 80 BPM, 100 BPM and 120 BPM. For each target, the diastole and systole times were adjusted:
    a. 60 BPM: Diastole of 700 ms, systole of 300 ms
    b. 80 BPM: Diastole of 500 ms, systole of 250 ms
    c. 100 BPM: Diastole of 400 ms, systole of 200 ms
    d. 120 BPM: Diastole of 320 ms, systole of 180 ms
4. *Observation*: The ability of the system to maintain the set BPM, along with the accuracy of the diastole and systole durations was observed. Any deviations or issues were noted.

Results

The test yielded the following observations:

- *60 BPM*: The heart beat steady with the correct diastole and systole durations. No significant deviations were noted.
- *80 BPM*: The heart beat steady with the correct diastole and systole durations. No significant deviations were noted.
- *100 BPM*: The heats actuation performed well, but the diastole phase was too short to fully empty the septum.
- *120 BPM*: The heats actuation performed well, but the diastole phase was too short to fully empty the septum.

Conclusion

The heart actuation system successfully achieved the target heart rates from 60 BPM to 120 BPM, with appropriate adjustments to diastole and systole durations, requirement FE0106, TE0209, TE0210 and TE0211 are a pass. The initial balloon test effectively ensured that the pressures remained within safe limits, protecting the hearts mechanism. The system showed reliable performance at lower BPM settings. At higher BPM settings the diastole time was too short for the vacuum line to empty the septum of air. By increasing the pressure to the vacuum line this problem will be solved, also as the mock loop will be filled with water. The pressure from the preload chamber will also help with the diastole phase.

Overall the system passed the test for achieving a wide range of BPM.

6 SYSTEM INTEGRATION

Connecting the hybrid heart to the mock circulation loop and to the pneumatic system integrates the whole test setup. By working together, they create a realistic environment for testing and validating the heart under different scenarios. With this setup it is also possible to test the performance of the tests setup itself.

6.1 REALISATION

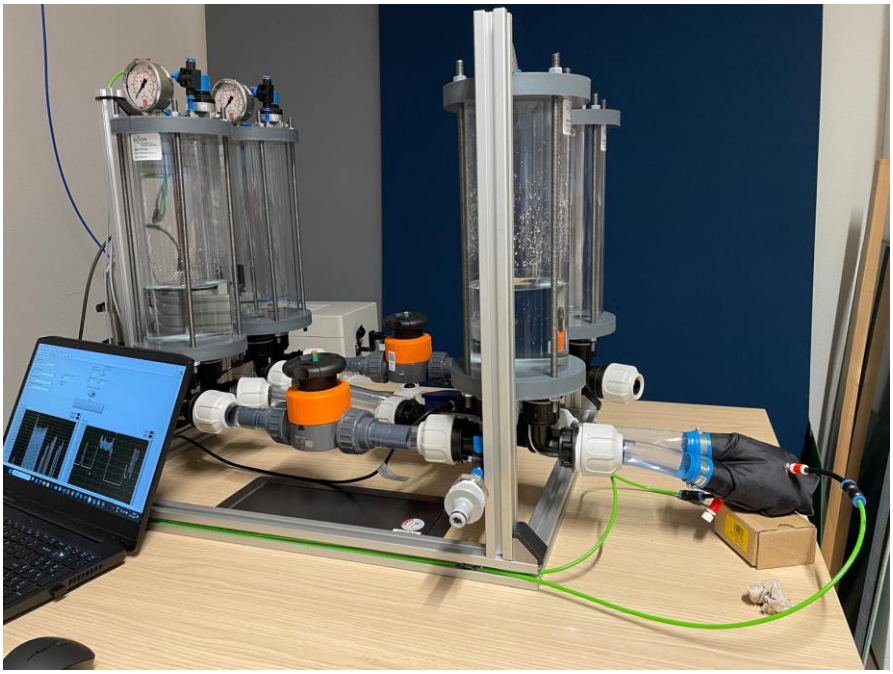


Figure 35: test setup for hybrid heart

Figure 36: Side view mock circulation loop

6.1.1 LabVIEW software

This chapter describes the construction of the software of the Mock Circulation Loop. The software is designed to ensure that all the requirements outlined in the requirement document are met and properly implemented within the Mock Loop. This software program contains the basic components to control and save the data generated by the test setup. This program serves as a foundational prototype, which can be further developed into the official program for comprehensive and long-term use.

Sensor configuration

The sensors are connected to the NI DAQ 6001 and the corresponding ports are configured in the software. Each sensor can also be calibrated according to their datasheet and their conversion formula can be put in the software. These calibrations are used to change the sensor's output voltage into readable data. The pressure sensors are calibrated to mmHg, the flow sensors to L/min and the pressure regulator to Bar.

1. Pressure sensor
    a. Sensor range: 0 – 750 mmHg
    b. Voltage (v): 0 – 5 V
    c. Calibration expression: $Pressure = \frac{V*750}{5}$

2. Ultrasonic Flow sensor
    a. Sensor range: 0 – 30 L/min
    b. Voltage range (V): 0 – 10 V
    c. Calibration expression: $Flow\ rate = V * 3{,}95 - 6{,}747$

3. Festo VPPE pressure regulator
    a. Sensor range: 0 - 2 Bar
    b. Voltage range (V): 0 – 10 V
    c. Calibration expression: $Pressure = (V - 0.1) * \frac{1.98}{9.9} + 0.02$

For each sensor/actuator, a custom LabVIEW script was written to ensure that each sensor works and that all the requirements of the acquisition system are met. These LabVIEW scrips are combined into one LabVIEW program containing all the individual tests.

Interface

The graphical user interface consists of a single window. Within this interface, the user has the option to configure the DAQ channels that are connected to the sensors and valves. The interface features two graphs displaying the pressure and flow from the hybrid heart. The graph on the left shows the pressure curves of both the aortic and pulmonary circulation. The graph on the right shows the “blood” flow of the aortic and pulmonary vessels.

Both graphs display the data of both sensors in one graph, this is deliberately done to allow the user to compare both sides directly with each other. This design choice facilitates easier comparison and analysis. Furthermore, it was found that depending on the duration of the tests, it might be of

interest to change the amount of data points per second. Therefore, the interface includes an option to modify the data sampling rate.

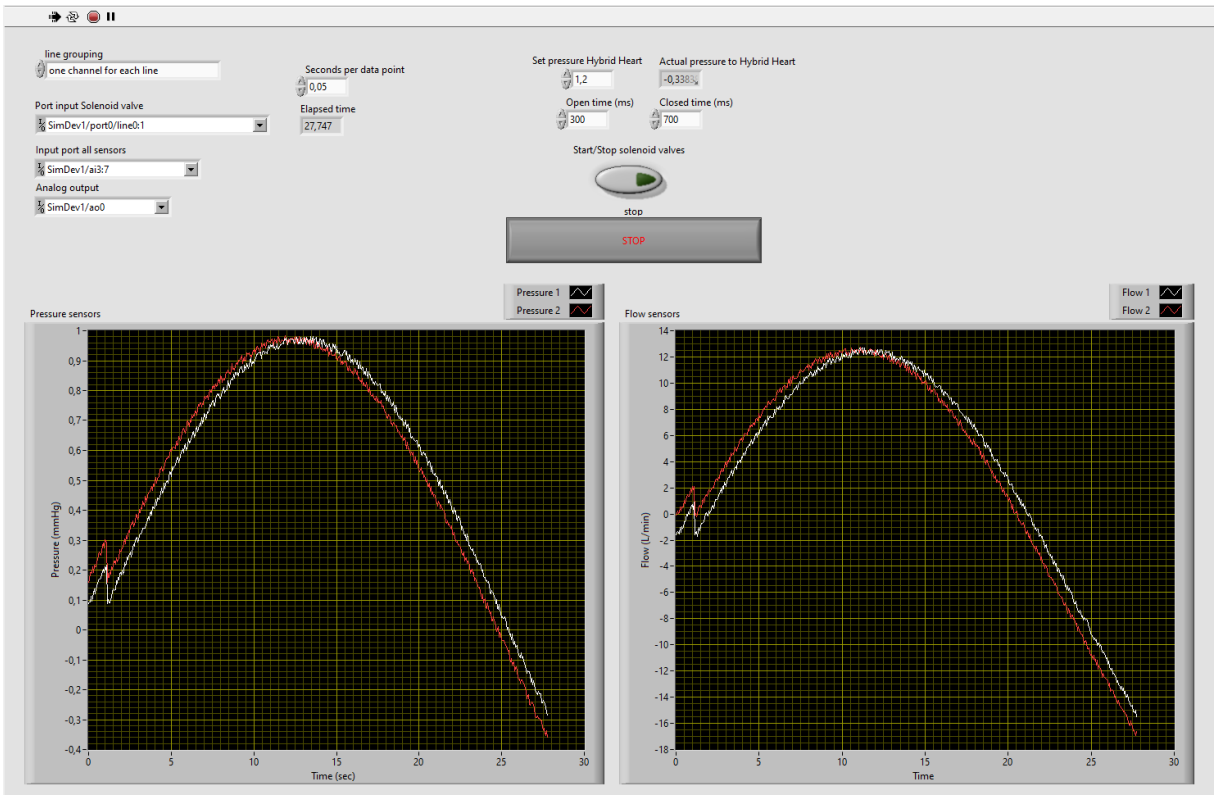


Figure 37: User interface

In the top part of the interface, there are the variables to control and actuate the hybrid heart. The first two numerical inputs allow the user to set the desired pressure needed to fill the heart and read out what the actual pressure is. For the Limo heart used in this project, this pressure is 1.2 Bar.

Below these inputs, there are two more numerical inputs to set the “heartbeat” of the hybrid heart. The ‘Open time (ms)’ tab represents the systolic phase, and the ‘Closed time (ms)’ is the diastolic phase of the heart. A normal heartbeat has a systole of 300 milliseconds and a diastole of 700 milliseconds. By summing the duration of these two phases and dividing 60 seconds by this total, the heart rate in heartbeats per minute can be determined. There is also a button to start and stop the actuation of the heart. This feature allows sensors to be tested without the hybrid heart starting to pump immediately when the program is started.

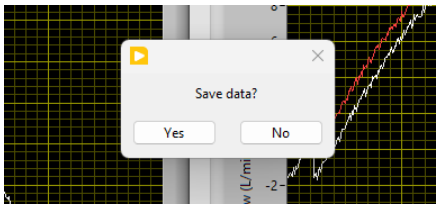


Figure 38: Save tab

When the stop button is pressed, both the heart actuation and the measuring sensors will be stopped. A message will appear on the user’s screen asking whether they would like to save the data. If the user selects “yes”, the data of that test will be saved as a text file.

6.2 TESTS

This chapter covers the tests performed to ensure the mock circulation loop works correctly. These tests were designed to check the system's flow, pressure stability, adjustability of the setup. The following sections explain the methods used, what is measured, and the results of these tests.

6.2.1 Performance mimicking human cardiovascular system

This test aims to verify the performance of the mock circulation loop simulating the hemodynamics of the human cardiovascular system. The following requirements will be assessed:

FE0102: The mock circulation loop should simulate the hemodynamics of the human cardiovascular system with reasonable accuracy, including blood flow dynamics, pressure profiles and vascular resistance.

FE0201: The mock circulation loop must replicate the physiological pressure and flow waveforms with reasonable accuracy, ensuring realistic testing conditions for the artificial heart.

TE0202: The right ventricle outflow pressure must be 30 mmHg or less.

For the requirements only the pressures of the pulmonary circulation are tested, because the LIMO heart cannot handle the pressures of the systemic circulation.

Method

To verify these requirements, the following procedure was implemented:

1. *Setup:* The mock circulation loop was assembled according to the standard procedure and filled with water.
2. *Instrumentation:* Pressure sensors and flow meters were installed within the loop to measure the pressure profiles and flow dynamics.
3. *Simulation:* The artificial heart prototype was activated to simulate normal cardiovascular conditions.
4. *Data collection:* Data on blood flow dynamics, pressure profiles and vascular resistance were collected over a set period.
5. *Analysis:* The collected data were compared to known physiological values for human cardiovascular hemodynamics.

Results

The performance test yielded the following results:

- Setup was able to simulate a pulmonary pressure at a heart rate of 60 BPM.
- Hybrid heart broke and air bubbles came into the circulation loop.
- Flow sensors went to error mode.

Conclusion

The test aimed to verify the mock circulation loop's ability to accurately simulate the pulmonary circulation's pressure conditions. The initial setup successfully achieved pulmonary pressures of around 30 mmHg at a heart rate of 60 BPM, demonstrating the system's potential to replicate human cardiovascular hemodynamics. However, during the test the hybrid heart failed, causing air bubbles to enter the circulation loop. The air bubbles led to flow sensors malfunctioning, which compromised the accuracy of the data collected.

Despite the failure of the hybrid heart during the test, the mock circulation loop successfully met the requirements. The data of the flow sensors was in this case, irrelevant for the test results. The data collected during the test, is available for review in the appendix under “Test results”.

6.2.2 Adjusting parameters mock loop

This test aims to verify that the mock circulation loop is capable of adjusting critical parameters such as cardiac output and systemic vascular resistance (FE0103). This ability is essential to simulate various clinical scenarios and ensure the versatility of the test setup.

Method

To verify requirement FE0103, the following procedure was followed:

1. *Setup:* The mock circulation loop was assembled according to the standard procedure and filled with water.
2. *Instrumentation:* The resistance valves were integrated into the system to modify cardiac output and systemic vascular resistance.
3. *Parameter adjustment:*
    a. Cardiac output: Adjusted by varying the pump speed of the artificial heart prototype.
    b. Systemic vascular resistance: Modified by adjusting the resistance valves within the circulation loop.
4. *Data collection:* Monitored and recorded the changes in flowrates, pressure profiles, and viscosity effects after each adjustment.
5. *Analysis:* Compared the adjusted parameters against known physiological values to ensure they fall within acceptable ranges.

Results

The test to adjust the critical parameters yielded the following results:

- Pressure output inside the afterload chamber started at 30 mmHg (pulmonary pressure).
- Turning the resistance effected in a higher pressure inside the afterload chamber.
- Pressure inside the heart increases significantly.
- Heart reaches 120 mmHg (systemic pressure).

Conclusion

This test aimed to verify the ability to change the resistance and cardiac output of the test setup. Because the hybrid heart had a failure, it was not possible to test this requirement with the use of the pneumatic system. By squeezing the heart, the heart actuation was simulated. The pressure in the afterload chamber increased as the resistance was raised. At one point, the pressure reached 120 mmHg, meeting the requirement TE0201. However, at this level of resistance the pressure in the preload chamber was no longer sufficient to quickly fill the heart. A vacuum might be needed to achieve this. During the test, we successfully adjusted the pressure to set the compliance, but we could not confirm whether it remained stable. Additionally, the results indicated that the resistance followed a quadratic pattern, while a linear pattern would be preferred. Based on these results, the test did not pass and should be repeated with a fully functioning hybrid heart.

7 CONCLUSION & FINAL EVALUATION

The aim of this graduation project was to develop an experimental setup able to measure and actuate the basics of a hybrid heart. This setup will be a basis for the research group of Mechatronics and Robotics to monitor and sensor the hybrid heart. In particular, It was found that that three physical elements were absolutely necessary to succeed in this goal: A actuation system for the total artificial heart, a data acquisition system, and a mock circulatory loop able to accurately represent a wide range of pathological and physiological conditions. Test protocols were specifically designed to ensure that all elements functioned as intended. Lastly, the resulting data of all test were analysed.

The pneumatic system that was designed to drive the hybrid heart had a positive performance. The pressures needed to completely fill and empty the heart were always achieved quickly. Regulating the diastole and systole phase with the use of solenoid valves turned out to work great and was easy to control. It was also possible to change the pressure during testing, with all these different options, it was possible to create the right conditions for the scope of this thesis.

The mock circulation loop has shown that with the current method of a closed air chamber and the calculated dimensions, it is possible to simulate the pressure of a human body. The use of resistance valves to increase pressure and simulate the pulmonary and systemic circulation has also proven to be effective. However, a limitation of the resistance is that even at its lowest setting, still generates a pressure of 30 mmHg in the afterload chamber. The resistance likely isn't linear, making it difficult to set the correct resistance level.

Creating a custom data acquisition system that allows for adjusting test parameters works surprisingly well and made it easy to create different test conditions. The data can also be read in real-time and at the end of the process, a text file is generated for further data analysis.

The test setup contains all the elements to simulate the tests within the scope of this thesis. The test setup creates a test platform for the research group of mechatronics and other research groups within Saxion.

Future research

The mock circulation loop was successful in replicating the pressures of the human cardiovascular system. However, several steps can be taken to further improve the setup to obtain more accurate results.

- A new software program were all the variable update automatically.
- A new resistance valve that has a linear drop of pressure, this increases the stability of the resistance and achieve the desired values. Also a valve with less resistance, this will increase the range of the compliance that is mimicked.
- Making the pneumatic circuit closed loop. This is a step closer to being able to put the system in an animal. Also, the setup makes a lot of noise, this will be reduced.
- Flow sensors in the pneumatic circuit, that measure the flow going in and out the heart. This will give data on how much air is needed and is lost inside the hybrid heart.
- A mathematical model of the mock circulation loop that calculates the compliance inside the chambers. The model in combination with a compressed air supply at the top of the chamber, create a feedback loop that can regulate the compliance. This is something for in the far future.

8 PERSONAL REFLECTION

During my graduation, I applied my knowledge of the past 5 years that I learned during my study. In doing so, I used to design concepts that were explained and applied during my studies. By first identifying the problem and defining what I wanted to solve with the product, I was able to quickly determine the necessary research and which tools and techniques would be useful. This information was then used to create a set of requirements, which serve as a guide for developing the final product. I am good at generating ideas and combining knowledge about different techniques. I can put my ideas on paper and communicate then to others reasonably well, but I still see room for improvement. However, I have noticed steady process in this area throughout my studies.

During various design projects throughout my study, especially during my year with student team 'Solar Boat Twente' where I worked with people from different fields, I discovered that I really enjoy working in a team. Sharing ideas and brainstorming with others boosts my creativity. My graduation project is a solo assignment, so it's more challenging to collaborate with someone. During my project, I tried to solve this problem by sparring and consulting a lot with M. van der Meulen, researcher of the research group Mechatronics. I am fairly good at calculating certain structures and applying materials, but I find development tasks more challenging. This includes programming and design subjects like SolidWorks, C++ and Python. The functions and options for these programs are so extensive that I need more time to improve my skills. To further develop these skills, I have chosen to focus on the competencies of designing and realising . These align well with my project, and I also enjoy doing them. I hope to develop these skills further during my master's period and when I enter the work field.

In a group, I prefer to take on an important role without necessarily being the leader. I think it's important to have my own tasks within the project, in addition to helping with the planning and identifying key areas of focus. I find the phase where concept is developed into a final product particularly interesting. I enjoy combining my creativity with my technical knowledge during this process.

During projects, I find it important to have good communication and to share knowledge with each other. In meetings, it's essential that someone leads the discussion and ensures collaboration, although I prefer not to take that role myself. During my project, we had a monthly meeting with the entire Holland Hybrid Heart consortium and I saw how much effort it takes to organize this for a large project. In smaller meetings with my supervisor, I think it's important to come prepared with questions and to present any relevant demonstrations or results for the project. I find it difficult to decide where I want to work in the future, but I hope to join a team that collaborates like this and is open to creative ideas. Personally, I prefer working on larger projects with multiple components where attention to detail is needed, rather dan focusing on improving just one part. This is something I hope to find in my future career.

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9 APPENDICES

Appendix 1 – Manual

Appendix 2 – System of requirements

Appendix 3 – MATLAB compliance code

Appendix 4 – Electrical circuit

Appendix 5 – Electrical circuit C14 port

Appendix 6 – I/O pinout

Appendix 7 – LabVIEW software

Appendix 8 – Test results

- Appendix 8a – Performance mimicking human cardiovascular system
- Appendix 8b – Adjusting parameters mock loop

Appendix 9 – Order list

Appendix 1 - Manual

This section will describe the startup procedure of the mock loop, which includes filling the loop along with how to run the heart using pneumatics.

1. The heart needs to be attached to the mock loop. The inflow valves are placed lower than the outflow valves. This is for easier removal of air from the ventricles.
2. Make sure all chambers are open to air.
3. Plug in the power cord of the control box and flip the switch. Put the USB cable into the laptop. There is power in the control box if NI device monitor program starts. Do NOT plug in the cables of the flow sensors, without water they will give an error. This error responds into all sensors not giving the right data.
4. Connect a water hose to the mock loop underneath the preload chamber. Don't forget to open the valve. Fill the mock loop to about 7 mmHg in all 4 compliance chambers. This water level is required by the afterload chamber to have around 2.5ml/mmHg compliance. Once the water level in the afterload is set, close the afterload chambers from air. The water level in the afterloads will no langer change and we can adjust the preload pressures as required.
5. Connect the flow sensors to the control box. Wait till the error light of the sensor turns green.
6. Open the LabVIEW program ´Mock Circulation Loop´. Connect the solenoid valve to channel P0.0 and P0.1 digital o/p of the DAQ, connect the pressure regulator to Ao0 and all the sensors to Ai3:7. In the interface set the pressure in the regulator (LIMO heart: 0.5-1.2 bar, Wired heart: 1.4-1.5 Bar) and set the systole time (300 ms) and diastole time (700 ms) for the beats, which is produced by the opening and closing of the solenoid valve.

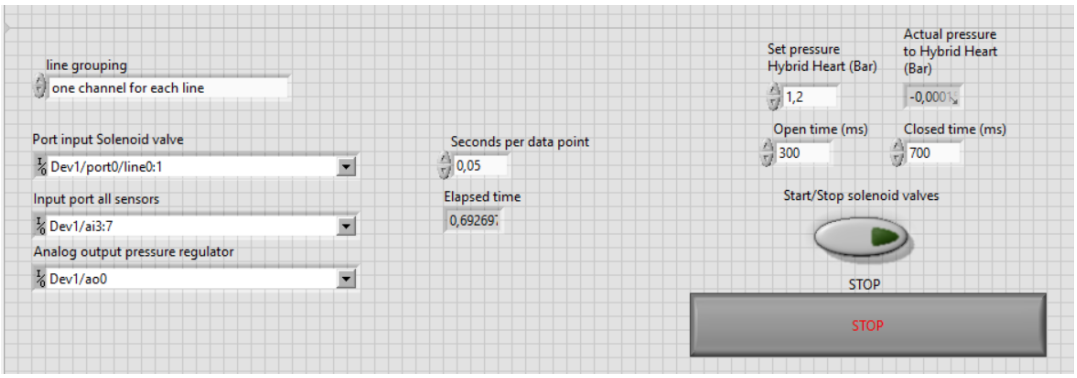


Figure 39: GUI for LabVIEW program

7. Once the heart starts running the pressure in the left afterload will begin to rise till it reaches a steady state. To increase the pressure tighten the resistor and open it to reduce pressure.
8. Set the seconds per datapoint to a desired value. When the STOP button is pressed the program asks to save the data.
9. To empty the mock loop open the valve underneath the preload chamber. This will allow the flow of water on gravity to exit the mock loop.
    a. Additional measures might be needed to fully empty the mock loop.
    b. Pressurizing the chambers or applying a vacuum to the preload chambers will allow water to collect in it for emptying.
    c. The heart can be removed to completely empty the loop.
10. If not in use turn of the power to the flow boards. Disconnecting the entire power rail will cause all apps to stop working and will need to be restarted.

Appendix 2 - System of requirements

Stakeholders

The stakeholders in this project are the research group of Mechatronics and Robotics and the research group Functions and Textiles. The mechatronics group is responsible for designing, developing and implementing the test setup. Both research groups can use this setup to do tests for the Holland Hybrid Heart project.

User scenario(s)

Scenario:

A researcher wants to conduct experiments to evaluate the performance of a new sensor prototype for the artificial heart

Interaction:

The researcher sets up the mock circulation loop, connects the artificial heart prototype, and configures parameters using the system's interface.

Actions:

The researchers monitor real-time data from sensors measuring bloodstream parameters and adjust experimental conditions as needed.

Outcome:

The researcher collects data on the artificial heart's performance Under various conditions for analysis and evaluation.

User requirements

User scenario 1: Researchers

Number	Requirement	Minimum/ maximum/ equal to	Value	Unit
GE0101	The system must be low in costs			
GE0102	The system must be easy to operate			

Notes:

Functional description

Functions

Functional requirements:
These requirements specify the specific actions, tasks, or behaviours that the mock circulation loop system must be able to execute to fulfil its functions effectively. They detail the desired functionalities and capabilities of the system in terms of inputs, outputs, and processing operations.

Device performance (In/outflow fluid dynamics):
Device performance requirements describe the expected performance data, criteria, or benchmarks that the mock circulation loop system must meet to demonstrate its effectiveness and reliability in operation. These may include parameters such as accuracy and capacity.

Interface requirements:
Interface requirements outline how the mock circulation loop system interacts with external components, systems, or users. They specify the interfaces, protocols, and communication methods needed for seamless integration with other devices, software applications, or human operators

Environmental requirements:
Environmental requirements address the conditions and constraints related to the physical surroundings in which the mock circulation loop system will operate. This includes watertightness and corrosion considerations to ensure the system's robustness and performance.

Safety and regulatory requirements:
Safety and regulatory requirements define the standards, guidelines, and protocols that the mock circulation loop system must comply with to ensure safe operation and compliance with relevant regulations. They include measures to protect operators, prevent accidents, and mitigate risks associated with system operation.

Functional requirements

Function 1: Functional requirements

Number	Requirement	Description
FE0101	The mock circulation loop should allow for the integration of the artificial heart prototype, enabling realistic testing of its pumping.	The mock loop connection to the hybrid heart is initially designed for one hybrid heart concept.
FE0102	The mock circulation loop should simulate the hemodynamics of the human cardiovascular system with reasonable accuracy, including blood flow dynamics, pressure profiles, and vascular resistance.	The mock circulation loop should mimic the pressures and blood flow of a human body.
FE0103	The test setup must be capable of adjusting parameters such as cardiac output systemic vascular resistance, and blood viscosity to mimic the physiological conditions.	With the ability to adjust the parameters, different tests can be performed on the test setup.
FE0104	The test setup is made so that one-half of the mock circulation loop can be disconnected.	The test setup is made with a double mock circulation loop. This way only one ventricle can be tested.
FE0105	The test setup is capable of adjusting the parameters to change and control the heart rate.	By changing the parameter the user is capable to set a specific heart rate in BPM and control the diastole and systole time of the heart.
FE0106	The test setup is capable of adjusting the pressure set on the heart.	By controlling the pressure to the heart, the heart pumping action and pressure will change.

Notes:

Function 2: Device performance

Number	Requirement	Description
FE0201	The mock circulation loop must replicate physiological pressure and flow waveforms with reasonable accuracy, ensuring realistic testing conditions for the artificial heart prototype.	The testing environment can closely simulate real-world scenarios, providing valuable insights into the performance of the artificial heart prototype under realistic conditions.
FE0202	The test setup should provide accurate measurements of key hemodynamic parameters, including cardiac output, arterial pressure, and vascular resistance, with a margin error not exceeding 5%.	

Notes:

Function 3: Interface

Number	Requirement	Description
FE0301	The mock circulation loop should be compatible with standard cardiovascular measurement devices, such as flow sensors, pressure sensors, and flow meters.	This Ensures easy integration of these devices into the testing setup, allowing for efficient data acquisition during experiments.
FE0302	The test setup must interface data acquisition systems or software for real-time monitoring and analysis of hemodynamic parameters during testing.	This capability facilitates prompt data collection and analysis, enhancing the efficiency and effectiveness of experimental procedures.
FE0303	The control board has to have enough input ports for the monitoring of all the sensors.	All the sensors need to be implemented in the system. This is also necessary if the system is expanded.

Notes:

Function 4: Environmental

Number	Requirement	Description
FE0401	The test setup needs to be watertight to prevent unwanted leakages in the system.	Water tightness is critical to maintain the integrity of experimental results and prevent contamination of surrounding areas.
FE0402	The test setup should be resistant to corrosion and degradation when exposed to blood-mimicking fluids.	Corrosion resistance is essential to maintain the structural integrity and functionality of the system over extended periods of use.
FE0403	The mock circulation loop must be equipped with a valve to drain the system.	This valve enables researchers to quickly and efficiently empty the loop of fluids.

Notes:

Function 5: Safety and regulatory

Number	Requirement	Description
FE0401	The mock circulation loop should comply with the relevant safety standards and regulations for laboratory equipment, ensuring the operator's safety during testing	Ensure the mock circulation loop adheres to applicable safety standards and regulations for laboratory equipment to safeguard the operator during testing.
FE0402	Safety features such as pressure relief valves and emergency shut-off mechanism should be incorporated into the test setup to prevent overpressure and ensure safe operation	These safety measures help reduce the possibility of equipment failure, system damage, and operator injury, thereby ensuring safe and reliable operation during testing procedures.

Notes:

External interfaces

External interfaces refer to the points of interaction between the mock circulation loop system and external components, systems, or users. Here are some potential external interfaces for the mock circulation loop system.

Requirements by external interfaces

External interface 1: User interface

Number	Requirement	Minimum/ maximum/ equal to	Value	Unit
EIE0101	Pressure indicator left afterload available	=	True	
EIE0102	Pressure indicator right afterload available	=	True	
EIE0103	Flow indicator systemic circulation available	=	True	
EIE0104	Flow indicator pulmonary circulation available	=	True	
EIE0105	Error indicator available	=	True	

Notes:

Technical requirements

Technical requirements 2: Device performance (in/out fluid-dynamics similar to cardiovascular system)

Number	Requirement	Minimum/ maximum/ equal to	Value	Unit
TE0201	Left ventricle outflow pressure	=	90(avg), 120(peak)	mmHg
TE0202	Right ventricle outflow pressure	<	30	mmHg
TE0203	Left ventricle filling pressure *(Left Preload pressure)*	>	15	mmHg
TE0204	Right ventricle filling pressure *(Right preload pressure)*	>	10	mmHg
TE0205	Inlet valve diameter *(left ventricle)*		<27 or >37	mm
TE0206	Inlet valve diameter *(right ventricle)*		<27 or >33	mm
TE0207	Outlet valve diameter *(left ventricle)*		<19 or >29	mm
TE0208	Outlet valve diameter *(right ventricle)*		<19 or 35>	Mm

TE0209	Heart rate of both ventricles	<	60 - 120	BPM
TE0210	Systole time at heart rate of 60 BPM	=	300	ms
TE0211	Diastole time at heart rate of 60 BPM	=	700	ms

Notes:

Technical requirements 3: Interface

Number	Requirement	Minimum/ maximum/ equal to	Value	Unit
TE0301	Data acquisition input ports	<	8	
TE0302	Pressure senor systemic circulation range	<	0 -150	mmHg
TE0303	Pressure sensor pulmonary circulation range	<	0 -40	mmHg
TE0304	Flow sensor systemic circulation range	=/<	0 -16	L/min
TE0305	Flow sensor pulmonary circulation range	=/<	0 -16	L/min
TE0306	Pressure sensor pneumatic actuator range	=/<	0 – 2	Bar
TE0307	Pressure regulator	=/<	0 - 2	Bar
TE0308	Vacuum generator	=/<	20	L/min

Notes:

Technical requirements 5: Safety and regulatory

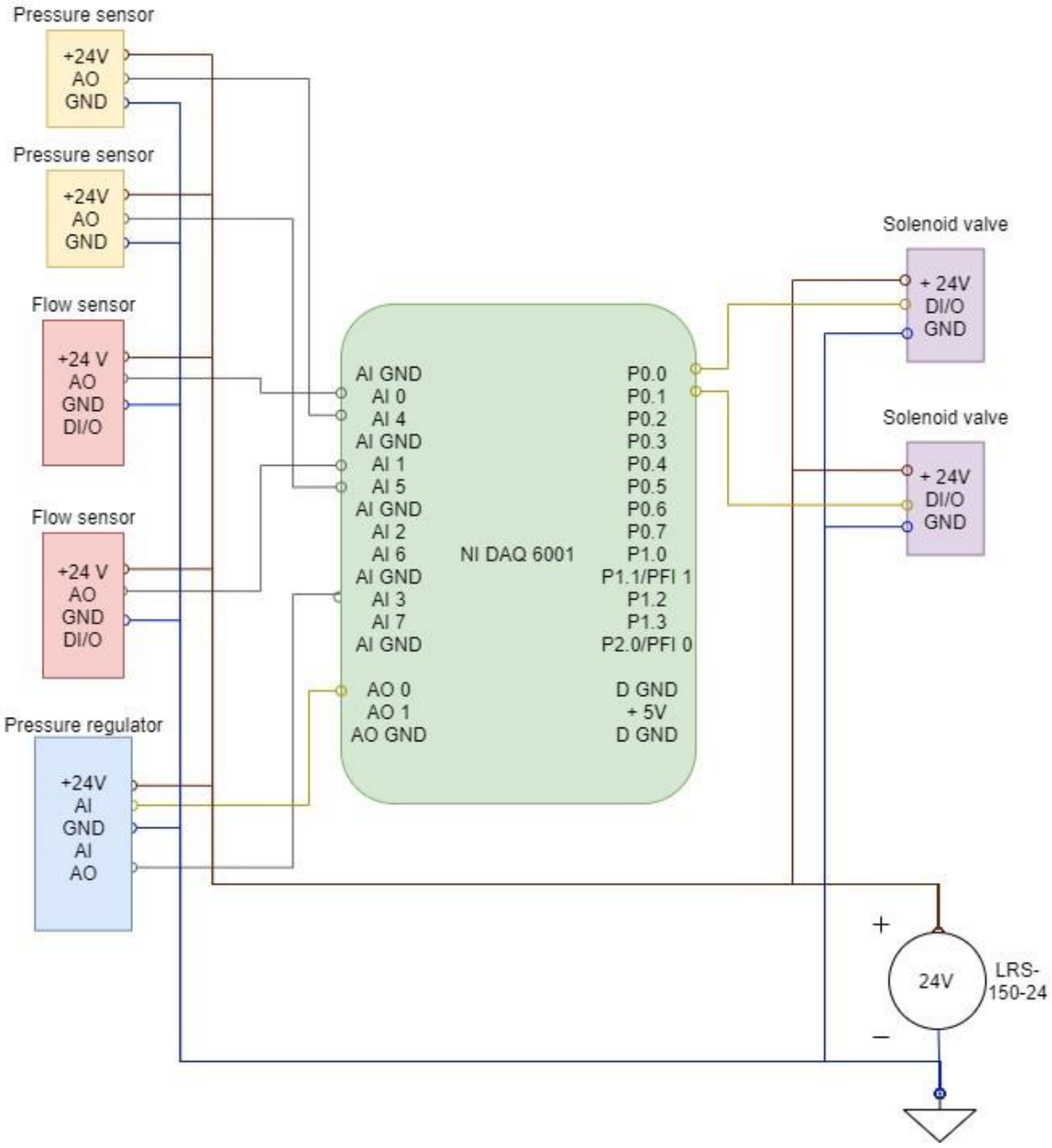
Number	Requirement	Minimum/ maximum/ equal to	Value	Unit
TE0501	The test setup must be equipped with a pressure relief valve	=	True	
TE0502	Critical components and moving parts of the mock circulation loop should be housed within protective enclosures to minimize the risk of operator injury.	=	True	

Notes:

Appendix 3 – MATLAB Compliance Code

```
% Constants
k = 7/5; % Adiabatic coefficient for air at 20°C
P0min_sys = 820; % Minimum absolute pressure for systemic chamber (mmHg)
P0max_sys = 890; % Maximum absolute pressure for systemic chamber (mmHg)
dPmax_sys = 70; % Maximum pressure difference for systemic chamber (mmHg)
dPmin_sys = 7; % Minimum absolute pressure for systemic chamber (mmHg)

Cmin_sys = 0.3; % Minimum compliance for systemic chamber (ml/mmHg)
Cmax_sys = 2.5; % Maximum compliance for systemic chamber (ml/mmHg)

P0min_pul = 760; % Minimum absolute pressure for pulmonary chamber (mmHg)
P0max_pul = 790; % Maximum absolute pressure for pulmonary chamber (mmHg)
dPmax_pul = 30; % Maximum pressure difference for pulmonary chamber (mmHg)
dPmin_pul = 4; % Minimum pressure difference for pulmonary chamber (mmHg)

Cmin_pul = 0.7; % Minimum compliance for pulmonary chamber (ml/mmHg)
Cmax_pul = 5; % Maximum compliance for pulmonary chamber (ml/mmHg)

% Calculate V0min for systemic chamber
V0min_sys = (Cmin_sys * dPmax_sys) ./ (1 - (P0min_sys ./ (P0min_sys +
dPmax_sys)).^(1/k));

% Calculate V0max for systemic chamber
V0max_sys = (Cmax_sys * dPmin_sys) ./ (1 - (P0max_sys ./ (P0max_sys +
dPmin_sys)).^(1/k));

% Calculate V0min for pulmonary chamber
V0min_pul = (Cmin_pul * dPmax_pul) ./ (1 - (P0min_pul ./ (P0min_pul +
dPmax_pul)).^(1/k));

% Calculate V0max for pulmonary chamber
V0max_pul = (Cmax_pul * dPmin_pul) ./ (1 - (P0max_pul ./ (P0max_pul +
dPmin_pul)).^(1/k));

% Display results
disp('Systemic Chamber:');
disp(['V0min = ', num2str(V0min_sys), ' mL']);
disp(['V0max = ', num2str(V0max_sys), ' mL']);
disp(' ');
disp('Pulmonary Chamber:');
disp(['V0min = ', num2str(V0min_pul), ' mL']);
disp(['V0max = ', num2str(V0max_pul), ' mL']);
```

Appendix 4 – electrical circuit



Appendix 5 – Electrical circuit C14 port

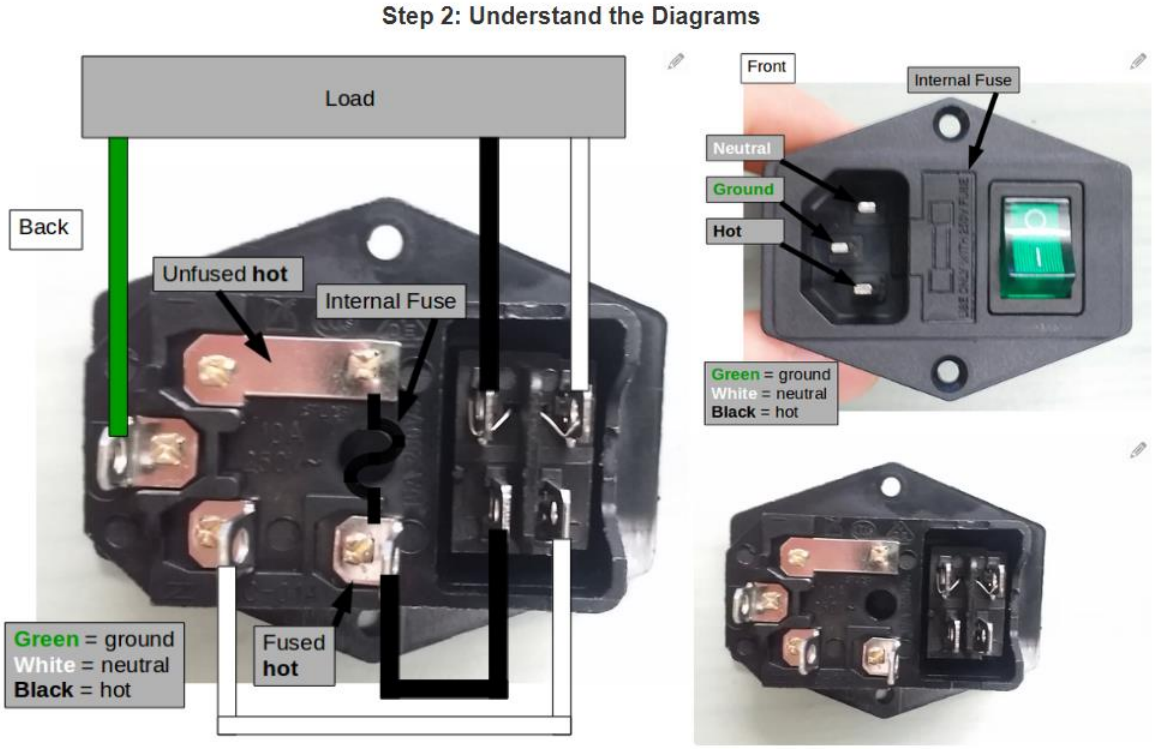
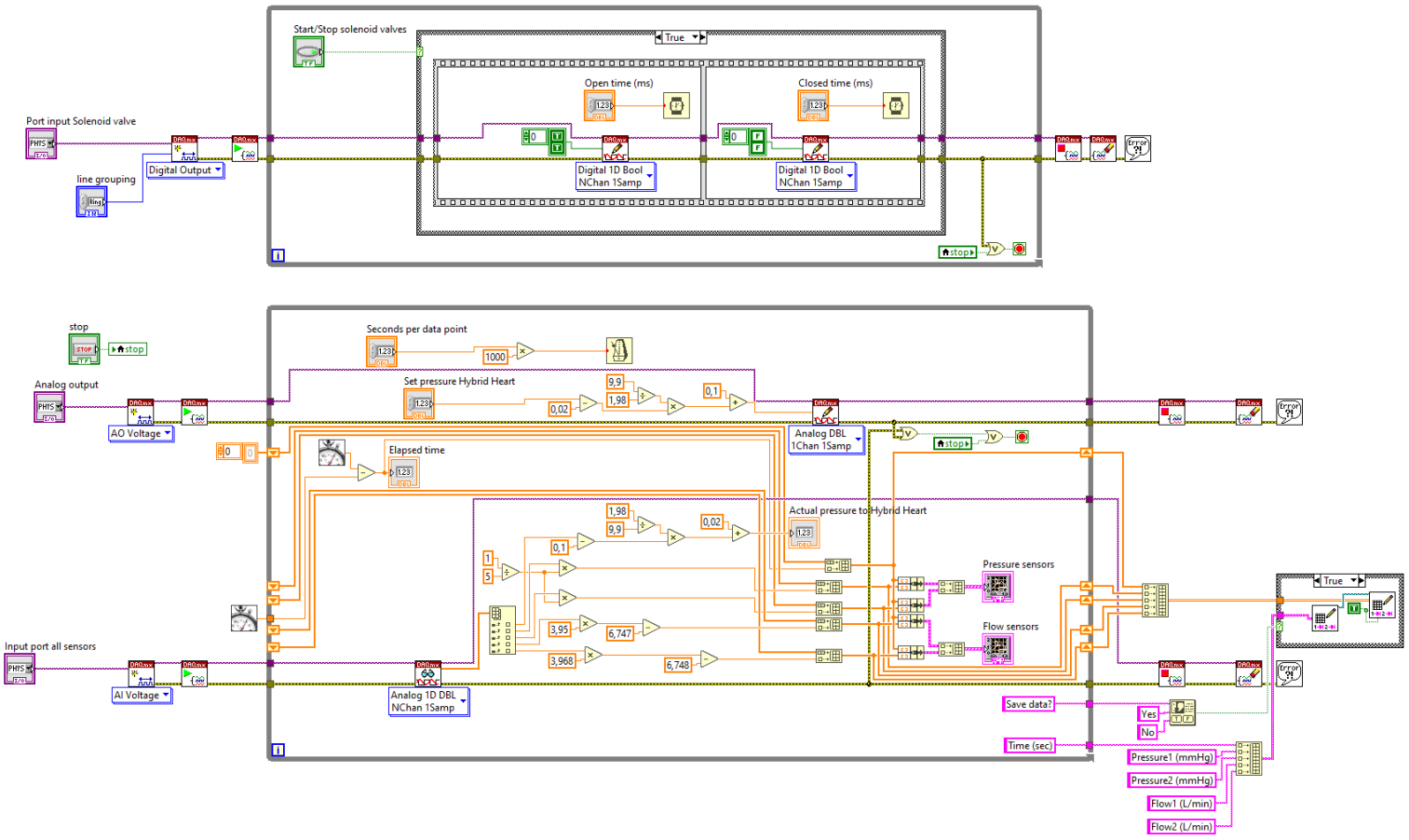


Figure 40: Electrical circuit C14 port (Wire Up a Fused AC Male Power Socket)

Appendix 6 – I/O pinout

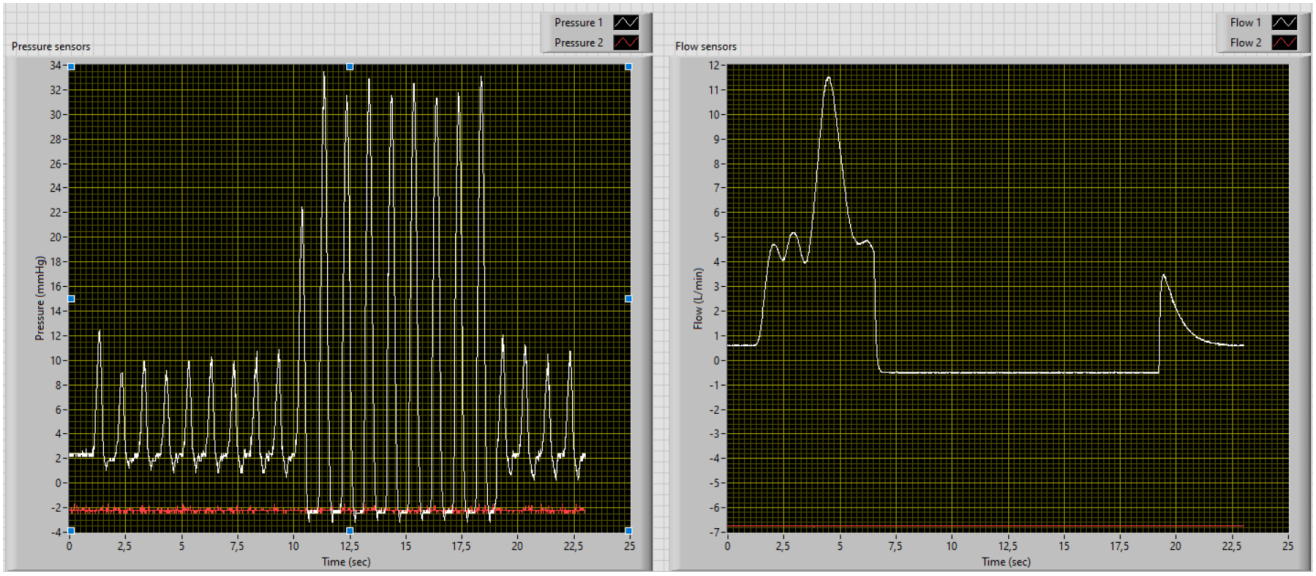
PIN	A/I3	A/I4	A/I5	A/I6	A/I7	Ao0	P0.0	P0.1
Device	Pressure Regulator	Pressure sensor 1	Pressure sensor 2	Flow sensor 1	Flow sensor 2	Pressure regulator	Solenoid valve 1	Solenoid valve2

Appendix 7 – LabVIEW Software

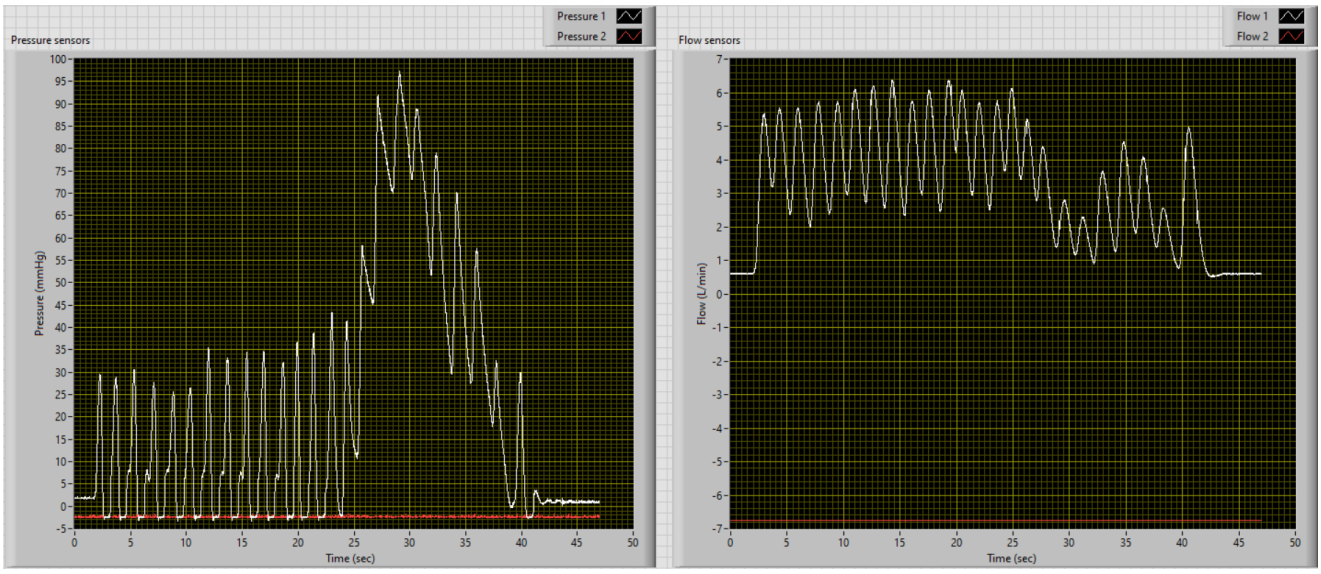


Appendix 8 – Test results

Appendix 8a – performance mimicking human cardiovascular system



Appendix 8b – Adjusting parameters mock loop



Appendix 9 – Order list

Project	Holland Hybrid Heart
Project number	
Applicant	J.M.Blommestijn
Supplier	Wildkamp / Conrad / Rs / Farnell / Eriks / Kunststofshop
Remarks	* The site is a configurator for composite plates. Fill in by materiaal:PVC and measurements: Dikte, 20mm. Lengte: 1000mm. Breedte: 500mm.

Amount	Unit	Product description	Website	Article number	Price per unit Excluding VAT	Including VAT	Supplier fee	Excl. VAT / unit	Total incl. VAT
		Wildkamp						€ -	€ -
3	Meter	Cristallo levensmiddelenslang 25x31 mm	https://www.wildkamp.nl/product/cristallo-levensmiddelensla	750574		€ 3,69		€ 3,05	€ 11,07
4	Pieces	DB fast zuigslangkoppeling 25mmx1"	https://www.wildkamp.nl/product/bd-fast-zuigslangkoppeling	15009287		€ 6,50		€ 5,37	€ 26,00
8	Pieces	DB fast zuigslangkoppeling 90°, 25mmx1"	https://www.wildkamp.nl/product/bd-fast-zuigslangkoppeling	15009318		€ 9,27		€ 7,66	€ 74,16
8	Pieces	VDL tankdoorvoer, PVC, 25mm x 1"	https://www.wildkamp.nl/product/vdl-tankdoorvoer-pvc-inwe	711152		€ 13,47		€ 11,13	€ 107,76
1	Pieces	Teflon tape, Gastec QA	https://www.wildkamp.nl/product/teflon-tape-gastec-qa-b-12	910205		€ 2,29		€ 1,89	€ 2,29
1	Pieces	Griffon hard PVC lijm 100ml	https://www.wildkamp.nl/product/griffon-hard-pvc-lijm-t-88-1	910022		€ 5,59		€ 4,62	€ 5,59
								€ -	€ -
		RS						€ -	€ -
2	Pieces	JUMO ultrasoon analog flow sensor 60 L/min	https://nl.rs-online.com/web/p/flow-sensors/2667095?gb=s	266-7095		€ 579,53		€ 478,95	€ 1.159,06
2	Pieces	M12, 4 pin plug, female	https://nl.rs-online.com/web/p/industrial-circular-connectors/	877-1110		€ 12,43		€ 10,27	€ 24,86
2	Pieces	M12, 4 pin cable, male to female	https://nl.rs-online.com/web/p/sensor-actuator-cables/877119	877-1198		€ 14,21		€ 11,74	€ 28,42
2	Pieces	Neutrik XLR connector female	https://nl.rs-online.com/web/p/xlr-connectors/0464713?gb=s	464-713		€ 4,66		€ 3,85	€ 9,32
2	Pieces	Diaphragm resistance valve	https://nl.rs-online.com/web/p/diaphragm-valves/2140532	214-0532		€ 210,66		€ 174,10	€ 421,32
2	Pieces	O-ring 120mm bore, 126mm outer	https://nl.rs-online.com/web/p/gaskets-o-rings/1965084	196-5084		€ 6,58		€ 5,44	€ 13,16
1	Pieces	M12, 5 pin plug, female, IP67	https://nl.rs-online.com/web/p/industrial-circular-connectors/	124-7078		€ 11,77		€ 9,73	€ 11,77
1	Pieces	Sensor cable M12, 5 pin male to female	https://nl.rs-online.com/web/p/sensor-actuator-cables/175008	175-0081		€ 18,76		€ 15,50	€ 18,76
1	Pieces	Festo G 1/4 Pneumatic regulator	https://nl.rs-online.com/web/p/pneumatic-regulators/1215659	121-5659		€ 54,50		€ 45,04	€ 54,50
1	Pieces	Festo vacuum pump 90L/min	https://nl.rs-online.com/web/p/vacuum-generators/2022438	202-2438		€ 68,98		€ 57,01	€ 68,98
2	Pieces	Pressure relief valve	https://nl.rs-online.com/web/p/pneumatic-pressure-relief-val	210-8443		€ 32,67		€ 27,00	€ 65,34
2	Pieces	M8 3 pin female plug	https://nl.rs-online.com/web/p/industrial-circular-connectors/	277-7246		€ 8,01		€ 6,62	€ 16,02
1	Pieces	Festo pneumatic tank 400mL	https://nl.rs-online.com/web/p/air-reservoirs/1259904	125-9904		€ 112,45		€ 92,93	€ 112,45
1	Pieces	QS-G1/8-6	https://nl.rs-online.com/web/p/pneumatic-fittings/1216178?gb	121-6178		€ 29,16		€ 24,10	€ 29,16
2	Pieces	QS-G1/4-6	https://nl.rs-online.com/web/p/pneumatic-fittings/1216171?cr	121-6171		€ 31,34		€ 25,90	€ 62,68
1	Pieces	QS-6-4	https://nl.rs-online.com/web/p/pneumatic-fittings/1442643	144-2643		€ 11,01		€ 9,10	€ 11,01
1	Pieces	QS-8-6	https://nl.rs-online.com/web/p/pneumatic-fittings/1442645	144-2645		€ 13,19		€ 10,90	€ 13,19
1	Pieces	QSY-6-4	https://nl.rs-online.com/web/p/pneumatic-fittings/1215991?gb	121-5991		€ 68,24		€ 56,40	€ 68,24
1	Pieces	Quick connect coupling G1/4 female	https://nl.rs-online.com/web/p/pneumatic-quick-connect-coup	135-8832		€ 13,20		€ 10,91	€ 13,20
2	Pieces	Analogue pressure gauge G1/4 2,5 Bar	https://nl.rs-online.com/web/p/pressure-gauges/4578951?gb=s	231-0191		€ 30,78		€ 25,44	€ 61,56
1	Pieces	C13 stekker 3m	https://nl.rs-online.com/web/p/power-cords/2677822?gb=s	267-7822		€ 11,53		€ 9,53	€ 11,53
								€ -	€ -
		Conrad						€ -	€ -
1	Pieces	LRS-150-24	https://www.conrad.nl/nl/p/mean-well-lrs-150-24-ac-dc-netvo	1439465-8J		€ 23,99		€ 19,83	€ 23,99
1	Pieces	C14 stekker inbouw	https://www.conrad.nl/nl/p/tru-components-tc-10088420-appa	2522105-8J		€ 4,99		€ 4,12	€ 4,99
								€ -	€ -
		Eriks						€ -	€ -
2	Pieces	* Plaat PVC-X 1000x500x20	https://select.eriks.nl/nl/plastics-configurator/categories/sheet					€ -	€ -
1	Pieces	Electronic presuure regulator	https://shop.eriks.nl/nl/pneumatische-componenten-ventieler	12264852		€ 560,18		€ 462,96	€ 560,18
2	Pieces	Solenoid valve 3/2	https://shop.eriks.nl/nl/magneetventiel-mhe2-m1h-3-2o-qs-4-	11639654		€ 89,15		€ 73,68	€ 178,30
								€ -	€ -
		Farnell						€ -	€ -
8	Pieces	M8 1m thread	https://nl.farnell.com/en-NL/tr-fastenings/m8-1-stst/studding-	1419414		€ 3,03		€ 2,50	€ 24,24
1	Pieces	NI DAQ USB-6001	https://nl.farnell.com/ni/782604-01/usb-6001-multifunction-i-o	3622272		€ 337,00		€ 278,51	€ 337,00
1	Pieces	M8 nuts	https://nl.farnell.com/tr-fastenings/m8-hfst-z50/nut-steel-zinc	152234		€ 2,66		€ 2,20	€ 2,66
								€ -	€ -
		Kunststofshop						€ -	€ -
2	Pieces	Acrylaat buis transparant 1000x120x3	https://www.kunststofshop.nl/acrylaat-plexiglas/acrylaat-buiz	5031200000		€ 45,00		€ 37,19	€ 90,00
								€ -	€ -
								€ -	€ -
								€ -	€ -
								€ -	€ -
								€ -	€ -
								€ -	€ -
								€ -	€ -
								€ -	€ -
								€ -	€ -
Total									**€ 3.722,76**